SEYFARTH SHAW

2015 Year in Review: Health Law

Stark Law Changes Introduced in 2016 Medicare Physician Fee Schedule

In the first major changes to the Physician-Self Referral Law ("Stark") regulations since 2009, CMS issued several clarifications, new exceptions and explanations in the 2016 Medicare Physician Fee Schedule Final Rule. Among the changes were the following:

- New exception recognized for recruitment assistance and retention payments from hospitals, FQHCs and RHCs to allow physicians to bring in new non-physician practitioners;
- Clarification that lease exceptions for a written agreement do not require a single contract, but may include multiple writings. To implement this, the term "agreement" was replaced in the regulatory language with "lease arrangement"; and
- New exception recognized for timeshare lease arrangements between a physician and hospital or unrelated physician organization, with certain exceptions.

The full text of the Final Rule with these and other Stark changes can be found at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-27931.pdf.

New DOJ Policy on Individual Accountability for Corporate Wrongdoing

In a memorandum dated September 9, 2015, the Department of Justice set forth a tough new policy to address individual accountability for corporate wrongdoing. This memo, sent to all U.S. Attorneys, outlined a stricter new approach for any companies seeking to receive any consideration for cooperation in a civil or criminal investigation. Specifically, "to be eligible for any credit for cooperation, the company must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the Department all facts relating to that misconduct." This includes companies such as health care entities being investigated under the False Claims Act, 31 U.S.C. § 3729(a)(2). U.S. Attorneys are further instructed that investigations should focus on individuals from the inception of the investigation, and that, absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.

For a copy of the DOJ Memo, please see: http://www.justice.gov/dag/file/769036/download.

About Seyfarth Shaw LLP's Health Law Department

Seyfarth Shaw LLP has been recognized as a leading Health Law practice by *U.S. News & World Report Best Law Firms* and *The Legal 500*, noted as having "extensive knowledge of the health care industry." In addition to attorneys who specialize in health law, our interdisciplinary team is drawn from each of the firm's departments—litigation, corporate, labor and employment, benefits and real estate—in all ten of our U.S. offices, in order to provide a coordinated and comprehensive full-service health law practice.

For more information:
http://www.seyfarth.com/healthcare

Join Our Mailing List

To be added to the Healthcare mailing list, please send an email request to:
seyfarthshaw@seyfarth.com.

Changes in Telemedicine Coverage and Restrictions

- Congress passed the TELEMedicine for MEDicare Act of 2015 (TELEMED Act) and the Veterans E-Health and Telemedicine Support Act of 2015 and over 200 bills were passed in all but eight states to make telemedicine ubiquitous as a means of addressing access to care.
- In almost all states (except Rhode Island), Medicaid now reimburses telemedicine services and most states reimburse for live video visits.
- Efforts by the Texas Medical Board (TMB) to restrict telemedicine services are being successfully challenged in court by TelaDoc, the nation's first and largest telehealth provider. After five separate challenges by the TMB, followed by enactment of a new rule to formally impose requirements deemed unreasonable for most telemedicine consultations, TelaDoc filed suit under federal antitrust law to block the imposition of the rule. An injunction on the application of the new rule has been imposed and TMB's attempts to have the suit dismissed have been unsuccessful. This ruling reflects a growing change in attitude towards state regulatory agencies as highlighted by the recent U.S. Supreme Court decision in North Carolina Board of Dental Examiners v. Federal Trade Commission where the Board (all private practitioners) was found to have violated Sherman Antitrust laws by imposing cease and desist orders on corporate entities alleged to have engaged in the corporate practice of dentistry.

We can expect more changes in 2016 in the following areas:

1. Private and public payors will continue to expand coverage of telemedicine services as consumer and employer demand increases.
2. Telemedicine will become an important means of expanding medical education and research on an international basis.
3. States will continue to support laws and rules that support telemedicine expansion in response to growing local/community needs for access to health services.
4. Employers with on-site clinics will look increasingly to telehealth services for their employee health and wellness programs.
5. Telemedicine will become an increasingly important feature of clinically integrated networks and ACOs to better coordinate care and achieve greater savings among.

New Physician Payment Model ("MIPS") from MACRA

On April 16, 2015, Congress enacted into law P.L. 114-10, the "Medicare Access and CHIP Reauthorization Act of 2015" ("MACRA"), which reforms the payment system for Medicare providers. MACRA repeals Medicare's "Sustainable Growth Rate" formula and replaces it with a new compensation system that rewards Medicare providers for value and quality patient care. Medicare providers may participate in the MACRA program by one of two methods: (1) "Merit-Based Incentive Payment System" ("MIPS"); or (2) "Alternative Payment Models" ("APMs"). The MACRA payment models will largely become effective in 2019. In addition, MACRA combines CMS' existing quality reporting programs into one new system by combining parts of the PQRS, the Value-based Payment Modifier, and the EHR incentive program based on the following factors: (a) quality; (b) resource use; (c) clinical practice improvement; and (d) meaningful use of certified EHR technology. MACRA rewards physicians who choose to adopt the new payment and delivery models, while also retaining its fee-for-service model. Participation in the payment models by Medicare providers is voluntary. APMs will also provide alternative methodologies to compensation Medicare providers. Accountable Care Organizations ("ACOs"), Patient Centered Medical Homes, and bundled payment models are some examples of APMs.

Hackable Medical Devices

With the Office of Civil Rights report (https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf), it is clear that data privacy breaches of healthcare providers and payors continue to be a problem. Medical information has become more valuable to hackers than even financial information, with a medical record going for upwards of ten times the value of a credit card number. This is leading hackers to try to find new and creative ways into hospital and physician office networks.

While networked data centers, laptops, and even phones are obvious targets for hackers to obtain medical records, there is also a new target - medical devices. This is due to the fact that medical equipment is increasingly becoming connected to the internet so that the data it produces can be fed into EMR systems. While this is a good feature for a number of reasons (data entry accuracy,

speed, etc.), this type of connectivity has now made the MRI an attack point. If a hacker can gain access to the MRI (or other connected medical device), that device can be used in an attack (such as a "credential elevation" attack) which can give the hacker access to the entire EMR database. This doesn't even take into consideration the patient safety implications of hacking devices like an IV pump.

As far back as 2014, Dave Kennedy, CEO of TrustedSEC LLC, said: "As attackers discover new methods to make money, the healthcare industry is becoming a much riper target because of the ability to sell large batches of personal data for profit. Hospitals have low security, so it's relatively easy for these hackers to get a large amount of personal data for medical fraud."

Consequently, it is important to use the same security protocols in setting up an internet-capable medical device as a new web server. In addition, device manufactures seem to be assuming their devices will be only inside "trusted" environments. A number of security practices which are implemented by device manufacturers in other markets seem to be absent in medical devices (e.g. use of same default password across models, etc).

With the affirmative security obligations imposed by the HIPAA/HITECH Megarule, healthcare providers are in need of including their medical devices in the same security program that all other connected devices are subject to. Otherwise, a security breach is much more likely to occur.

OCR's Security & Privacy Audits

Under HIPAA/HITECH the Office of Civil Rights ("OCR") conducts audits to determine compliance with the privacy and security rules. Previously, the OCR only audited a sample of "Covered Entities". However, OCR has indicated that it is expanding its audit program to include Business Associates. This is particularly important because the 2014 changes to the privacy and security rules bring Business Associates directly under the regulatory framework of HIPAA/HITECH. Business Associates are no longer merely bound by their agreement with a Covered Entity, but rather are directly regulated. Note that this does not mean that the Covered Entities are off the hook. In September 2015, the OIG published a report criticizing OCR sharply for its overly "reactive" approach to HIPAA compliance and lack of oversight of Covered Entities' compliance with the Privacy Rule. Thus, we anticipate that OCR will maintain, and probably increase, its focus on Covered Entities.

Critically, the Phase 2 Audits will target HIPAA Standards that were frequent sources of non-compliance in the Phase 1 Audits, including risk analysis and risk management, content and timeliness of breach notifications, notice of privacy practices, individual access, the Privacy Standards' reasonable safeguards requirement, workforce member training, device and media controls, and transmission security.

OCR projects that later Phase 2 Audits will focus on the Security Standards' encryption and decryption requirements, facility access control, breach reports and complaints, and other areas identified by earlier Phase 2 Audits. Phase 2 Audits of Business Associates will focus on risk analysis, risk management and breach reporting to covered entities.

2015 saw multiple significant settlements with providers over healthcare compliance, including non-institutional providers. Clearly, OCR is focusing on the full range of provider types and is taking the possibility of HIPAA penalties seriously.

CMS Introduces Prior Authorization for DMEPOS

After multiple reports by the Office of the Inspector General showed a longstanding history of improper payments, CMS is adding an additional step for requesting providers. Now, all relevant coverage, coding, and clinical documentation requirements must met before a patient can receive his or her device and before the claim is submitted by the provider for payment. In fact, under the new rule, claims for certain DMEPOS items must have an associated provisional affirmed prior authorization decision as a condition of payment. This rule also adds the review of a contractor's decision regarding prior authorization to the list of actions that are not initial determinations and therefore not appealable.

According to CMS, this new scrutiny will not burden patients; rather, the new prior authorization requires the same information already mandated by Medicare, just earlier in the process. There are no new clinical documentation requirements in order to receive devices.

Although some degree of administrative red-tape can certainly be expected, CMS has created an expedited process in the event that a delay in processing will endanger patient health. To further alleviate the burden on providers and suppliers, CMS is limiting this new rule to only 35 items on the master list of supplies - for now. The ultimate goal is to reduce fraudulent claims, and with an estimated $10 million dollars to be saved in 2016 alone, provider should expert prior authorization to become the new normal.

Congress Enacts New Restrictions on HOPDs

President Obama signed the Bipartisan Budget Act of 2015 (Act) into law on November 2, 2015. Section 603 of the Act implements a so-called "site-neutral" Medicare payment reform for off-campus hospital outpatient departments (HOPDs) by changing the reimbursement methodology for such entities.

Starting on January 1, 2017, apart from dedicated emergency departments, services and items provided at HOPDs that are located more than 250 yards from a hospital's main campus or remote location will be reimbursed under the Physician Fee Schedule (or Ambulatory Surgical Center Payment System) and not under Medicare's Prospective Payment System for Hospital Outpatient Department Services (OPPS).

Although the Act grandfathers such HOPD locations that were billing under the OPPS prior to November 2, 2015, industry associations, such as the American Hospital Association, are expressing concern regarding the Act and, in particular, the fact that its effective date did not provide for any time to prepare for such a change.

We anticipate that the implementing regulations to be promulgated by CMS will provide some clarity on this issue and perhaps future legislation will provide some relief for those caught up in this sudden change.

Daniel Sternthal
Editor and Author

dsternthal@seyfarth.com

Adam H. Laughton
Editor and Author

alaughton@seyfarth.com

Jesse M. Coleman
Author

jcoleman@seyfarth.com

Sheryl Tatar Dacso
Author

sdacso@seyfarth.com

Kimberly C. Gordy
Author

kgordy@seyfarth.com

Bonnie G. Sinclair
Author

bsinclair@seyfarth.com

John P. Tomaszewski
Author

jtomaszewski@seyfarth.com

SEYFARTH SHAW

Atlanta	Los Angeles	Shanghai
Boston	Melbourne	Sydney
Chicago	New York	Washington, D.C.
Houston	Sacramento	
London	San Francisco	www.seyfarth.com