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Regulatory Reform Could Hasten Transition to Value-Based Care

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In recent months, officials at the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) have made clear in highly publicized remarks that accelerating the transition of the health care system from a primarily fee-for-service payment model to an integrated care model is a key priority. Dubbed the "Regulatory Sprint to Coordinated Care," these officials have announced their intention to address the federal regulations they believe are acting as unnecessary barriers to coordinated care. To date, officials have suggested that industry stakeholders can expect to see changes to the federal physician self-referral law (Stark Law),[1] the federal Anti-Kickback Statute (Anti-Kickback Statute),[2] the beneficiary inducement prohibitions in the Civil Monetary Penalty Law (CMP Law),[3] the Health Insurance Portability and Accountability Act (HIPAA), and the rules under 42 C.F.R. Part 2 related to opioid and substance abuse disorder treatment.

Of particular note, over the summer of 2018, CMS and the HHS Office of Inspector General (OIG) released requests for information (RFI) seeking public feedback on how certain federal fraud and abuse laws (the Stark Law, the Anti-Kickback Statute, and the CMP Law) may inhibit the implementation of innovative payment arrangements and coordinated care arrangements (such as accountable care organizations, clinically integrated networks, bundled payment arrangements, and two-sided risk models).

Industry stakeholders certainly welcome this HHS initiative. The broad scope of the laws involved and the potential for serious penalties for even a technical misstep frequently prevent providers from pursuing or fully embracing alternative payment models, even when the adoption of such models could improve patient care and reduce the cost of medical care.

The first RFI, which CMS released on June 25, 2018, specifically seeks feedback on how the Stark Law may be impeding beneficial arrangements that would advance coordinated care.[4]

The Stark Law was enacted over two decades ago when a primarily fee-for-service landscape reimbursed providers for the volume of services performed. The Stark Law was needed to help protect Medicare and its beneficiaries from unnecessary costs, overutilization, and potential conflicts of interest that may occur when providers benefit financially from referring patients to health care entities in which they have a financial relationship. However, newer, alternative payment methodologies hold providers accountable for their overall management of a patient's condition by rewarding them for working together to control costs and improve quality, rather than for procedures or referrals. Theoretically then, in a properly designed alternative payment model, overutilization and unnecessary costs should be less of a risk.

The Stark Law, a strict-liability statute with hefty penalties, generally prohibits certain care coordination activities and arrangements with providers. Under the Stark Law, unless an arrangement is structured to fit within a specific exception, providers are prohibited from making referrals to an entity in which they have a financial relationship. This term is broadly defined, such that almost any relationship between a provider and an entity that bills Medicare for certain common services is subject to the law.

While there are a few Stark Law exceptions that providers look to when structuring alternative payment arrangements (most notably, the risk sharing and physician incentive compensation exceptions),[5] these exceptions are too narrowly drafted to cover all care coordination and alternative payment methodologies that providers want to pursue. In addition, since any arrangement must be structured to fit specifically within the exception, arrangements are tailored to the law, not in a way that would necessarily produce the best outcomes. As a result, from time to time, CMS has granted technical waivers of Stark Law compliance to providers participating in specific alternative payment models such as the Medicare Shared Savings Program and the Comprehensive End Stage Renal Disease (ESRD) Care Model. This patchwork approach does not seem sustainable for the long term—it is administratively burdensome on CMS and stifles innovation among industry stakeholders.

Indeed, in the comments submitted to date, many providers have expressed frustration at the limitations the Stark Law places on them when their end goal is to better coordinate care for their patients. For example, in their comments, the American Academy of Orthopaedic Surgeons noted that the Stark Law impedes their efforts to better coordinate with skilled nursing facilities and home health agencies to take care of their patients post-surgery.[6]

They noted that once compliance waivers were granted under the Bundled Payment for Care Improvement Program (BPCI), the program has seen higher quality, lower cost, and better care coordination. The group advocated for CMS to abandon its current case-by-case approach in favor of a formalized exception that would allow this sort of care coordination more broadly and not just under the BPCI program.[7]

Similarly, the American Hospital Association (AHA) has proposed adding a new value-based payment exception that would protect various types of financial arrangements, so long as the remuneration is reasonably related to, and used to achieve, certain coordinated care goals.[8] AHA also advocated for revisions to the risk-sharing exception mentioned above, so that it would apply more broadly to include arrangements involving Medicare fee-for-service patients.[9]

Two months after the release of the Stark Law RFI, on August 24, 2018, the OIG released a separate RFI seeking input from the public on the Anti-Kickback Statute and the CMP Law.[10] As in the previously released Stark Law RFI, the OIG is asking the public for focused comments on modernizing the Anti-Kickback Statute and the CMP Law to encourage and incentivize coordinated care.

The Anti-Kickback Statute is a criminal statute that prohibits the payment of remuneration to induce or reward the referral of federal health care business.[11] Enacted when fee-for-service payment models dominated the health care industry, it is intended to protect patients and federal health care programs from fraud and abuse by curtailing the influence of remuneration on health care decisions. Like the Stark Law, certain arrangements are protected from prosecution if they are structured to fit within certain safe harbors. While not a strict liability statute (unlike the Stark Law, failure to fall within a safe harbor is not necessary a violation of the law), the high costs of running afoul of the Anti-Kickback Statute still restricts and shapes the way that industry stakeholders are willing to structure alternative payment arrangements and reward providers for coordination of care efforts. Indeed, OIG, from time to time, also has granted waivers to the Anti-Kickback Statute to allow certain Medicare-sponsored alternative payment arrangements to move forward, including the Medicare Shared Savings Program, the Comprehensive ESRD Care Model, and the BPCI program.

In addition to regulating how industry stakeholders interact with providers, the Anti-Kickback Statute, along with the beneficiary inducement provisions of the CMP Law, regulates how providers can interact with their patients. Under these laws, providers generally are prohibited from paying or offering any remuneration that is likely to influence a patient's selection of a particular provider of items or services that are payable by Medicare or Medicaid. For example, providing certain medical supplies or other items free of charge could be characterized as remuneration that is prohibited by the Anti-Kickback Statute and the CMP Law. While there are certain exceptions related to the provision of financial assistance to promote access to care,[12] as health care providers are being asked to take on greater risk in managing the care of their patients and attempt to better coordinate care, providers want more flexibility to assist patients with other social determinants of health and reduce barriers to quality care.[13]

It is difficult to know exactly what changes HHS and CMS may ultimately make to the Stark Law, Anti-Kickback Statute, and CMP Law, but industry stakeholders should be encouraged that HHS and CMS have acknowledged that these federal fraud and abuse laws are impeding certain innovative payment arrangements that would advance coordinated care and are starting to take formal steps to modernize the laws.

Public comments on the Stark Law RFI were due August 24, 2018. Comments on the Anti-Kickback Statute/CMP Law RFI are due October 26, 2018.

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1 42 U.S.C. § 1395nn.

2 42 U.S.C. § 1320a-7b(b).

3 42 U.S.C. § 1320a-7a(a)(5).

4 83 Fed. Reg. 29524, *available at* https://www.federalregister.gov/documents/2018/06/25/2018-13529/medicare-program-request-for-information-regarding-the-physician-self-referral-law.

5 42 C.F.R. § 411.357(n) and 42 C.F.R. § 411.357(d)(2).

6 Letter from American Academy of Orthopaedic Surgeons to Seema Verma re: CMS-1720-NC, Request for Information Regarding the Physician Self-Referral Law, at 5 (Aug. 14, 2018), *available at* https://www.regulations.gov/document?D=CMS-2018-0082-0114.

7 *Id.*

8 Letter from American Hospital Association to Seema Verma re: CMS-1720-NC, Request for Information Regarding the Physician Self-Referral Law, at 15 (Aug. 3, 2018), *available at* https://www.regulations.gov/document?D=CMS-2018-0082-0049.

9 *Id.* at 18.

10 83 Fed. Reg. 29524, *available at* https://www.federalregister.gov/documents/2018/08/27/2018-18519/medicare-and-state-health-care-programs-fraud-and-abuse-request-for-information-regarding-the.

11 42 U.S.C. § 1320a-7b(b).

12 *See, e.g.,* 42 C.F.R. § 1003.110.

13 *See, e.g.,* Statement of American Hospital Association for the Committee on Ways and Means, Subcommittee on Health of the U.S. House of Representatives, "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program", July 17, 2018, *available at* https://www.aha.org/system/files/2018-07/180718-aha-statement-house-ways-means-stark-law.pdf.

Recent Developments in the 340B Drug Program

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The 340B Drug Pricing Program (340B Program or Program) has been controversial for much of its 26-year history, with 2017 and 2018 being no exception. The Program's purpose has always been to provide eligible covered entities the opportunity to buy certain outpatient drugs at significantly reduced prices with the savings used to "stretch scarce federal resources as far as possible" to treat low-income patients.[1] Questions at issue include who benefits from the Program and how do they benefit, is the Program monitored well enough for compliance, does the Program cause overutilization, can the system be gamed by manufacturers and providers, and is the Program transparent enough.

The 340B Program is unique because discounts are not a direct government or taxpayer subsidy for covered entities; rather, pharmaceutical companies provide the discounts while the federal Health Resources and Services Administration (HRSA) provides oversight for program integrity. With a new administration in Washington in 2017, once again the 340B Program has come under scrutiny. The Trump administration stated that it wants to reduce the cost of prescription drugs in part by revising certain aspects of the 340B Program.[2] One of the first actions by the Centers for Medicare & Medicaid Services (CMS) was to make reimbursement changes to the Medicare Hospital Outpatient Prospective Payment System (OPPS), leading to the first significant 340B activity of 2017.[3]

CMS payment cuts to hospitals were effective January 1, 2018 for drugs purchased under the 340B Program. Payments were decreased from the drug's average sale price (ASP) plus 6% to ASP minus 22.5%.[4] The reduction was predicted to save Medicare beneficiaries $320 million.[5] While many disagree upon the ultimate impact of the payment cuts on 340B participating hospitals, bipartisan efforts and litigation have ensued to save the pre-existing payment structure. Legislation such as *The 340B Pause Act of 2017*,[6] which was introduced by Representative Larry Bucshon (R-IN), would rescind the OPPS cuts for 340B drugs. Another bill, which was sponsored by David B. McKinley (R-WV), proposes that the OPPS cuts under the 340B Program shall have no force or effect.[7] Various private groups challenged the OPPS reductions in court. In *American Hospital Ass'n v. Hargan*,[8] the American Hospital Association (AHA), the Association of American Medical Colleges (AAMC), America's Essential Hospitals (AEH), and three of their member hospitals sued CMS alleging it had no authority under the Social Security Act to implement the OPPS reductions. The court dismissed the case on jurisdictional grounds, finding plaintiffs failed to exhaust their administrative remedies.[9] The D.C. Circuit upheld the dismissal of the lawsuit.[10] On September 5, 2018, AHA, AAMC, and AEH, along with three hospitals refiled their lawsuit asserting that plaintiffs cured the procedural defects and asking for expedited relief.[11]

In another legal maneuver AHA, AAMC, AEH, and 340B Health sued the U.S. Department of Health and Human Services (HHS) over the long-delayed final regulations that require drug pricing transparency for drug manufacturers, as well as penalties associated with overcharging of covered entities. In the complaint, *American Hospital Ass'n v. Azar*,[12] plaintiffs note that implementation of the regulations has been delayed five times in 20 months and ask that the regulations be made effective in 30 days. The regulations set forth a methodology to calculate ceiling prices so that the federal government would be able to determine if manufacturers were deliberately overcharging 340B entities for drugs.

Perhaps the most significant pro-340B legislation proposed in 2018 was the *Stretching Entity Resources for Vulnerable Communities Act of 2018* (SERV Communities Act),[13] sponsored by Representative Doris Matsui (D-CA).[14] The SERV Communities Act proposes rolling back the OPPS reimbursement cuts for certain hospitals and implementing a ceiling price calculation methodology with civil monetary penalties attached for manufacturer violations of the ceiling price. The language of the SERV Communities Act clarifies that 340B is designed to help safety-net providers direct scarce resources to needed programs, which may be, but is not required to be, direct drug discounts to patients. Organizations that support the SERV Communities Act include the Washington, DC-based advocacy group 340B Health, AHA, the California Hospital Association, and the AAMC. The SERV Communities Act was referred to the House Ways and Means Subcommittee on Health.

Two other 340B Program legislative proposals are the *Helping Ensure Low-income Patients Have Access to Care and Treatment Act of 2018* (HELP Act) and the *Closing Loopholes for Orphan Drug Act*. The HELP Act,[15] which currently is in the Senate Health, Education, Labor, and Pensions Committee, proposes a two-year moratorium on registration of new non-rural 340B hospitals and associated sites. During the moratorium, new regulations would be promulgated to clarify hospital eligibility criteria and child-site standards and to enhance transparency. The *Closing Loopholes for Orphan Drugs Act of 2017*,[16] proposes to extend the orphan drug (drugs used to treat rare conditions) discount to all covered entities instead of only certain entities, closing a long-standing loophole in the law.

As part of the ongoing congressional review of the 340B Program, on June 18, 2018, the U.S. Government Accountability Office (GAO) issued a report that used CMS and HRSA data from 2012 to 2016 to compare 340B and non-340B hospitals.[17] The report, which was requested by House Energy and Commerce Committee Chairman Greg Walden (R-OR) and Subcommittee on Health Chairman Michael Burgess (R-TX), concluded that differences in 340B and non-340B hospitals varied significantly based on hospital type (Critical Access, Sole Community, and General Acute Disproportionate Share), making generalizations and conclusions about the Program's impact and effectiveness difficult. The report did find that participation in the 340B Program increased in states that opted into Medicaid expansion, but not in non-expansion states.

Following the GAO report, the House Energy and Commerce Committee sent letters to nine contract pharmacies seeking information on "contract pharmacy arrangements and the role of contract pharmacies in the 340B program . . . ." In the letters, the Committee noted its concern with the explosion in the number of contract pharmacies, citing a "1300 percent increase in unique contract pharmacies between 2010 and 2017." The Committee sent letters to Walmart, CVS, and Walgreen's, among others. The lawmakers requested extensive information from the pharmacies by August 15, 2018.[18]

Given the serious activity regarding 340B in 2018, providers who participate in the Program should continue to be mindful of their compliance obligations, stay up-to-date on legislative proposals, and contact their representatives to ensure participating provider voices are heard.

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1 Health Resources & Servs. Admin. 340B Drug Pricing Program (2018), *available at* https://www.hrsa.gov/opa/index.html.

2 Rich Daly, *340B Targeted in Trump Administration Drug Push*, Healthcare Financial Management Ass'n (2018), May 15, 2018, *available at* http://www.hfma.org/Content.aspx?id=60695.

3 82 Fed. Reg. 59222 (Dec. 14, 2017) (to be codified at 42 C.F.R. pts. 414, 416, and 419).

4 *Id.*

5 Jack O'Brien, *Could this Bipartisan Bill Protect 340B Drug Discounts? The Clock is Ticking,* HealthLeaders (Dec. 18, 2017), *available at* https://www.healthleadersmedia.com/finance/could-bipartisan-bill-protect-340b-drug-discounts-clock-ticking.

6 H.R. 4710, 115th Cong. (2017-2018).

7 H.R. 4392, 115th Cong. (2017-2018).

8 No. 17-2447 (RC) (D.D.C. Dec. 29, 2017).

9 *Id.*

10 *American Hospital Ass'n v. Azar*, No. 18-5004 (D.C. Cir. July 17, 2018).

11 *American Hospital Ass'n v. Azar,* No. 18-02084 (RC) (complaint filed, D.D.C. Sept. 5, 2018).

12 No. 18-02112 (RC) (complaint filed, D.D.C. Sept. 11, 2018).

13 H.R. 6071, 115th Cong. (2017-2018).

14 340B Health, *New Legislation Would Strengthen 340B Program, Demand Transparency, Accountability for Drug Makers* (June 13, 2018), *available at* https://340binformed.org/2018/06/new-legislation-would-strengthen-340b-program-demand-transparency-accountability-for-drug-makers/.

15 S. 2312, 115th Cong. (2017-2018).

16 H.R. 2889, 115th Cong. (2017-2018).

17 GAO, *Drug Discount Program: Characteristics of Hospitals Participating and not Participating in the 340B Program* (GAO-18-521R), *available at* https://www.gao.gov/products/GAO-18-521R.

18 *See, e.g.*, Letter by Greg Walden, Michael C. Burgess, and Gregg Harper, House Energy and Commerce Committee (Aug.1, 2018) to Mr. Stefano Pessina, Executive Vice Chairman and Chief Executive Officer, Walgreen's Boots Alliance, Inc. Letters to all nine pharmacies contained the same information and are *available at* https://energycommerce.house.gov/news/letter/letters-to-340b-contract-pharmacies/.

The Future of Health Care: Recent Legal Developments Impacting the Use of Artificial Intelligence

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From electronic health records to robot-assisted surgery, hospitals are embracing the benefits of technology in providing better care for patients. And as health care technology has developed, the government has expanded the network of laws and regulations governing its use. Much of the recent interest in the application and regulation of health care technology has been in the area of artificial intelligence.

In general, the term "artificial intelligence" refers to the use of computers systems to simulate human intelligence. Artificial intelligence encompasses two related computer-driven applications: machine learning and deep learning. The term "machine learning" refers to the use of algorithms to predict outcomes, simulating the way the human brain processes data. The goal of machine learning is to find connections in data without being explicitly programmed. Deep learning is a further subset of machine learning that employs computer "neural networks" to recognize patterns in large sets of data. Deep learning is often applied to health care in the use of computers to read and detect abnormalities in x-ray and CT images. The most recent government-approved uses of artificial intelligence in health care come from the application of deep learning.

In the clinical context, applications of artificial intelligence have been regulated by the federal Food and Drug Administration (FDA) as medical "devices." Medical devices are classified into Class I, II, and III based on the level of risk associated with the device.

- Class I and II medical devices are classified as low to moderate risk and are subject to less extensive FDA oversight.
- Class III is reserved for devices that "sustain or support life, are implanted, or present potential unreasonable risk of illness or injury."[1] Class III devices must go through an extensive premarket approval process, by which the FDA assesses the safety and effectiveness of the device before it can be marketed.

Class III also includes any novel device without a predicate on the market. As a result, most technologies employing artificial intelligence were automatically designated Class III, regardless of the level of risk associated with the device. To get novel, lower-risk technologies to market more quickly, Congress passed the Food and Drug Administration Modernization Act of 1997, which added the "De Novo" classification option—a less onerous alternative to the standard premarket approval process. To submit a De Novo classification request, the sponsor submits a request to the FDA that includes a description of the device, its probable benefits and anticipated risks, as well as any supporting clinical or nonclinical data.[2]

Even with the introduction of the De Novo option, rapid advances in digital health technology continued to highlight the tension between new technology and the increasingly outdated FDA regulatory framework for medical devices. Congress addressed this tension in December 2016, after significant lobbying from technology companies, by passing the 21st Century Cures Act.

21st Century Cures Act

The 21st Century Cures Act (Cures Act) aimed to accelerate the development of medical technology and bring innovation to patients faster and more efficiently. As part of these aims, the Cures Act specifically targets the development of artificial intelligence by:

- Clarifying the FDA's jurisdiction over digital health products by excluding a subset of medical software from the definition of medical "device."[3]
- Accelerating the development of innovative medical products by establishing the Breakthrough Devices Program.[4]

Device Exclusions

The federal Food, Drug, and Cosmetic Act (FDCA) establishes the FDA's jurisdiction over medical "devices." Section 3060 of the Cures Act amends the FDCA to expressly exclude certain software functions from the "device" definition. Most relevant to this discussion, the Cures Act excluded from the medical device definition what is generally referred to as "clinical decision support" (CDS) software. Software qualifying for exclusion as CDS under the Cures Act must meet the following four criteria:

> (1) intended to display, analyze, or print medical information about a patient or other medical infor-

mation (such as peer-reviewed clinical studies and clinical practice guidelines);

(2) intended to support or provide recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition;

(3) intended to enable such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient; and

(4) *not* intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system.[5]

CDS is not intended to replace clinician judgment; rather, CDS is a tool "to assist care team members in making timely, informed, and higher quality decisions."[6] The FDA published draft guidance in December 2017 to provide clarity on the types of CDS excluded by the Cures Act.[7] Examples of non-device CDS the FDA listed in the draft guidance include:

- Software that provides a health care professional with current practice treatment guidelines for common illnesses based on the patient's diagnosis;
- Software that suggests an intervention or test based on the physician's order; or
- Software that suggests alternatives to orders, drugs, or therapies consistent with practice guidelines and other generally accepted practices.[8]

Breakthrough Devices Program

Section 3051 of the Cures Act amends the FDCA to establish a program for "breakthrough devices," intended to assist with more timely access to breakthrough technologies by reducing the lag time associated with the assessment and review of eligible devices. To qualify for designation as a breakthrough device, the device must "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating disease or conditions" and one of the following must be true of the device:

(1) it represents breakthrough technologies;

(2) no approved or cleared alternatives exist;

(3) it offers significant advantages over the existing alternatives; or

(4) the availability of the device is "in the best interest of patients."[9]

The FDA issued draft guidance in October 2017 implementing the Breakthrough Devices Program, which superseded the prior expedited review schemes: the Expedited Access Pathway and the Priority Review Program.[10] The guidance sets forth the principles of the Breakthrough Devices Program, including interactive and timely communication between the device sponsor and the FDA, efficient and flexible clinical study design, and priority review of breakthrough devices. FDA has approved at least one artificial intelligence software application under this program.[11]

FDA Guidance and Software Precertification Pilot Program

In the wake of the Cures Act, the FDA issued its Digital Health Innovation Action Plan, which outlined the agency's framework for the regulation and review of new digital health technologies.[12] The plan has three primary objectives:

1. Issuing guidance implementing the 21st Century Cures Act;
2. Launching the Software Precertification Pilot Program; and
3. Building the FDA's expertise in its digital health unit.

The FDA addressed the first objective by issuing a spate of draft guidance throughout 2017, including:

- Breakthrough Devices Program Draft Guidance (October 2017)[13]
- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act Draft Guidance (December 2017)[14]
- Clinical and Patient Decision Support Software Draft Guidance (December 2017)[15]

The second objective, the Software Precertification Pilot Program (Precertification Program), takes a novel approach to digital health technology oversight. Rather than addressing approval of individual products, FDA's Center for Devices and Radiological Health (CDRH) "pre-certifies" eligible digital health developers who "demonstrate a culture of quality and organizational excellence."[16] These pre-certified developers could then qualify to market their devices either without additional FDA review or through a streamlined premarket review process, depending on the level of risk associated with the product. The Precertification Program selected its participants in September 2017, which include Apple, Fitbit, Johnson & Johnson, and Samsung.[17] The FDA plans to establish the framework for precertification by the end of 2018.[18]

Recent FDA Approvals of Artificial Intelligence Devices

As the agency focuses more on innovation, a greater number of devices employing artificial intelligence are clearing the FDA approval process.

The first two examples below were low-to-moderate risk devices approved using the FDA's De Novo premarket review process. The third example is among the first artificial intelligence software applications approved through the new Breakthrough Devices Program.

De Novo Premarket Review

Stroke—In February 2018, the FDA permitted the marketing of a clinical decision support software designed to alert providers of a potential stroke in patients.[19] Under the current standard of care,

a patient's CT images are reviewed by a neuro-radiologist who then reports any potential stroke indicators to a neurovascular specialist. With the Viz.AI Contact application, the algorithm reviews the CT images, and, if a stroke indicator is detected, the application sends a text alert to the neurovascular specialist for further review. As the FDA notes in its press release, the application does not replace review by the neuro-radiologist; the human review and algorithm review occur simultaneously. Rather, by using artificial intelligence to analyze the CT images, the Viz.AI Contact application potentially speeds up the notification process. As part of the FDA's De Novo premarket review, the company demonstrated that the application could notify a specialist sooner in cases involving a suspected large vessel blockage.

Wrist fractures—In May 2018, the FDA approved the marketing of an artificial intelligence algorithm for detecting wrist fractures. OsteoDetect is a detection and diagnostic software that uses an artificial intelligence algorithm "to analyze two-dimensional X-ray images for signs of distal radius fracture, a common type of wrist fracture."[20] The software uses machine learning to identify areas of fracture in x-rays. As part of its application for De Novo premarket review of OsteoDetect, the company submitted a study comparing 1,000 x-ray images assessed using the algorithm against those same images assessed by board certified orthopedic hand surgeons. The study suggested that detection of wrist fractures was improved using OsteoDetect, as compared to the review of the images unaided by the software.

Breakthrough Devices Program

Diabetic retinopathy—In April 2018, the FDA authorized the marketing of the first medical device using artificial intelligence "to detect greater than a mild level of the eye disease diabetic retinopathy in adults."[21] Diabetic retinopathy, caused by high levels of blood sugar damaging the blood vessels of the retina, is the most common cause of vision loss among diabetics. The device, known as IDx-DR, is a software program that uses an artificial intelligence algorithm to analyze images of the eye. The images are uploaded to a cloud server and the IDx-DR software provides the doctor with one of two readings: "more than mild diabetic retinopathy detected," or "negative for more than mild diabetic retinopathy." IDx-DR was approved using the Breakthrough Devices Program and is the first device approved by the FDA that provides a screening decision without the need for interpretation by a specialist.

Conclusion

The past two years have seen significant development in the laws and regulations governing the use of artificial intelligence in health care. The 21st Century Cures Act and its regulatory progeny have paved the way for greater innovation by developing creative options to streamline FDA approval and get products to market sooner. As the regulatory framework becomes more flexible, the opportunities for artificial intelligence in health care will only expand. Hospitals and health systems can leverage these new technologies to improve both the quality and efficiency of care delivery. Everyone wins!

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1 U.S. Food and Drug Admin. (FDA), *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, *available at* https://www.fda.gov/medicaldevices/resourcesforyou/consumers/ucm142523.htm (last visited Sept. 1, 2018); *see also* 21 U.S.C. § 360c(a)(1)(C).

2 FDA, *Evaluation of Automatic Class III Designation (De Novo)*, *available at* https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/ucm462775.htm (last visited Sept. 1, 2018).

3 21st Century Cures Act, Pub. L. No. 114-255, tit. III, § 3060.

4 *Id.* at § 3051.

5 *Id.* at § 3060.

6 Ctrs. for Medicare & Medicaid Servs. (CMS), *Clinical Decision Support: More Than Just "Alerts" Tipsheet*, at 2, *available at* https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ClinicalDecisionSupport_Tipsheet-.pdf.

7 FDA, *Clinical and Patient Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff* (Dec. 8, 2017), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf.

8 *Id.* at 8-9.

9 21 U.S.C. § 360e-3(b).

10 FDA, *Breakthrough Devices Program: Draft Guidance for Industry and Food and Drug Administration Staff* (Oct. 25, 2017), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

11 See *infra* Recent FDA Approvals of Artificial Intelligence Devices.

12 FDA, *FDA In Brief: FDA brings additional efficiency and modernization to regulation of digital health, as part of the Digital Health Innovation Action Plan* (Apr. 26, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm605723.htm; FDA, *Digital Health Innovation Action Plan*, *available at* https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf.

13 *Supra* note 10.

14 FDA, *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Draft Guidance for Industry and Food and Drug Administration Staff* (Dec. 8, 2017), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf.

15 *Supra* note 7.

16 *Digital Health Innovation Action Plan, supra* note 12, at 5.

17 FDA, *FDA selects participants for new digital health software precertification pilot program* (Sept. 26, 2017), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm577480.htm.

18 FDA, *Precertification (Pre-Cert) Pilot Program: Frequently Asked Questions*, *available at* https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/ucm577330.htm (last visited Sept. 1, 2018).

19 FDA, *FDA permits marketing of clinical decision support software for alerting providers of a potential stroke in patients* (Feb. 13, 2018), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm596575.htm.

20 FDA, *FDA permits marketing of artificial intelligence algorithm for aiding providers in detecting wrist fractures* (May 24, 2018), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm608833.htm.

21 FDA, *FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems* (Apr. 11, 2018), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604357.htm.

Benefits of Planned Records Management

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The sunset of paper documents held promise for savings on records storage and ease of records retrieval. Unfortunately, the complexity of electronic systems has delayed the fulfillment of this promise. The number of media types and formats in which information is created and stored are exploding. Electronic systems have made it easier to retain multiple versions and duplicate copies and made it more difficult to dispose appropriately of this "extra" and "stale" information (and copies). As information system costs continue to grow and revenues for health care services shrink, health care organizations will benefit from a comprehensive records management program that addresses paper and electronic materials.[1]

The components of the records management program may include record coordinators and their roles, retention schedules, document/information classification, confidentiality requirements, legal hold processes, and destruction methods. Other components also may be needed such as guidance on data migration, archiving and reconstruction, manuals, checklists, and review lists.

Benefits of Records Management

One of the most often-cited benefits of records management is the savings achieved from reduced storage costs when only necessary information is retained for appropriate periods of time. There is a cost for storage of large volumes of data whether stored physically or electronically. Physical storage costs include rental or lease expense for storage space, utilities, and maintenance. Electronic storage costs include hardware, software, power consumption, labor, and monitoring costs.[2]

Organizations with an effective records management program also will realize savings on system updates, maintenance costs, and data conversion. A good records management program will include guidelines for data migration and conversion as information systems are replaced. To the extent that needed information is migrated into a new application, an organization should establish a timeframe that details the availability of access for active use of the records as well as for retention. Establishing this guidance and applying it to the sun-setting application provides the added benefit of reducing time and effort to reconstruct vital information in the event of a disaster, cyber-attack, theft, or other data losses.[3]

Perhaps the largest cost avoidance will be from reduced effort needed for data searching and retrieval. A good record retention policy can reduce legal risks and discovery costs. Extensive record searches can be avoided with a records management program that identifies and provides for retention of relevant documents and destruction of irrelevant documents.

Complimenting proper data retention is scheduled data destruction, including automatic deletion. Automatic deletion of data not required to be retained will reduce search time and reduce the risk of retaining conflicting and confusing documents. Appropriate destruction methods also minimize the vulnerability of the organization to data theft and loss.

Consideration of State and Federal Laws and Regulations

The foundation for records management is the framework of state and federal laws and regulations setting specific retention periods for specific types of records. One of the most important required retention periods is the False Claims Act (applied to Medicare claims) requirement for retention of records in connection with billing for patient care for a minimum of ten years. There are many laws specific to records retention. Just as important are the applicable statutes of limitation, which set the time periods that the records will be needed for litigation purposes. In addition to laws and regulations, organizations may have contractual obligations for records retention. For example, participation agreements with Medicare Advantage plans include record retention obligations.

The organization must determine how to implement the thousands of federal and state laws applicable to records retention. Most organizations establish a retention period based on the legally required time plus an extra year to ensure records are not prematurely destroyed. While implementing these requirements, organizations are faced with two significant challenges—the granularity of records retention requirements and application of the retention period to a variety of records types.

Document Classification and Categories

Most laws and regulations were enacted to apply to paper records. It is not unusual for a retention schedule to include more than 30 pages of 15 lines per page with disparate time periods—to form the basis for a records retention policy. Many organizations are adopting categories for retention, which apply retention periods to groups of records. For example, temporary records such as voice mails, text messages (not relied upon for treatment), and paper slips used to input information into computer systems, may be characterized as temporary and a short retention period may be established for auto destruction of these temporary records.

To add to the complexity of records management, many different triggers for initiating the record retention period can apply, e.g. date of document creation, date of contract termination, and date of completion of the plan of care. As the number of electronic records increases, the organization may want to consider a records classification for newly created electronic records. The classification and creation date could establish the basis for a retention review date. Good information about classification systems is available from multiple sources, including the National Archives in the United Kingdom.[4]

Assigning a retention review date when the record is created is an approach that organizations can consider to proactively manage record retention and destruction. By assigning records management coordinators to review groups of records after an initial retention period, the organization can ensure important and needed records are retained and unneeded records are destroyed in accordance with the established requirements.

Legal/Litigation Holds

The records management framework must be accompanied by an appropriate litigation hold policy and process that preserves records when a litigation hold triggering event occurs. It is essential that the litigation hold program include release of the hold and destruction of the held documents. Organizations must never destroy documents or information in response to a request for information or after the information is summoned by court order. Destruction of documents at this point may result in fines, penalties, and/or imprisonment. Key to a litigation hold is suspension of auto deletion of records. Organizations also should plan for preservation of metadata in addition to the record itself to ensure retention of the complete record.

Appropriate Destruction Requirements

As a final component, the records management program should include appropriate access and destruction requirements. Until records are no longer needed, the organization must provide for secure storage and restricted access. For records that include protected health information (PHI), the organization risks fines and penalties for improper handling and destruction. "The careless handling of PHI is never acceptable. Covered entities and business associates need to be aware that OCR is committed to enforcing HIPAA regardless of whether a covered entity is opening its doors or closing them. HIPAA still applies."[5]

In the July 2018 Department for Health and Human Services Office for Civil Rights (OCR) Cyber Security Newsletter, OCR shared *Guidance on Disposing of Electronic Devices and Media*.[6] This guidance discusses destruction and disposal of PHI. OCR issued additional guidance for effectively rendering unsecured PHI unusable and indecipherable.[7] OCR advised that PHI disposed of in accordance with this guidance is not considered "unsecured" PHI and would not be subject to Health Insurance Portability and Accountability Act breach notification requirements.[8] The guidance further confirms that PHI is considered to have been disposed of in a secure manner when the media on which the PHI is stored or recorded has been destroyed in one of the following ways:

- Paper, film, or other hard copy media have been shredded or destroyed such that the PHI cannot be read or otherwise cannot be reconstructed.
  NOTE: Redaction is specifically excluded as a means of data destruction.
- Electronic media have been cleared, purged, or destroyed consistent with NIST Special Publication 800-88 Revision 1, Guidelines for Media Sanitization such that the PHI cannot be retrieved.

In addition to properly destroying PHI, it is important for an organization to keep a destruction log of those records that have been disposed of in accordance with the records management program.[9] The log should document the destruction of electronic records (emails, digital/video recordings, social media posts, etc.) as well as paper records (including books, photos/slides, microfilm, etc.). At a minimum, the log should include:

- Information regarding authorization for the destruction;
- Names/brief description of the documents being destroyed;
- Date range of the records being destroyed (start date to end date);
- Method of destruction, and
- Date of destruction.

Conclusion

Design and administration of a records management program takes time and effort. Implementation will require connecting with multiple stakeholders to ensure a complete process is in place. Concerns about compliance with laws and regulations and discovery requests should be solicited and guidance and education shared with the appropriate stakeholders. The benefits of the program will be best realized when the risks and fears related to information loss and document destruction are addressed and resolved.

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1 81 Fed. Reg. 7654, 7671 (Feb. 12, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02789.pdf; *see also* False Claims Act, 31 U.S.C. §§ 3729–3733; § 3731(b).

2 DocsVault, *Top 10 Benefits of Records Management*, *available at* https://www.docsvault.com/top-10-benefits-of-records-management-2/.

3 Southern Illinois University, *Records Management*, *available at* http://www.siue.edu/records/benefits.shtml (last visited Sept. 3, 2018).

4 The National Archives, *Disposal of Records*, *available at* http://www.nationalarchives.gov.uk/documents/information-management/rm-code-guide8.pdf (last visited Sept. 3, 2018).

5 Dep't of Health & Human Servs., Press Release, Consequences for HIPAA violations don't stop when a business closes (Feb. 13, 2018), *available at* https://www.hhs.gov/about/news/2018/02/13/consequences-hipaa-violations-dont-stop-when-business-closes.html.

6 *Available at* https://www.hhs.gov/sites/default/files/cybersecurity-newsletter-july-2018-Disposal.pdf?language=es.

7 OCR, *Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals*, *available at* https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html.

8 *See* 45 C.F.R. §§164.400-414.

9 *See, e.g.*, http://www.lva.virginia.gov/agencies/records/tips/documents/destructiontips.pdf.

Resource Corner

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