haynesboone

HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

FEBRUARY 2017

QUICK SHOTS

False Claims Act *Year in Review* highlights key developments in 2016.
Read more.

21st Century Cures Act requires Medicare to include patient backgrounds in reduction calculations under Hospital Readmissions Reduction Program.
Read more.

Final Guidance Sheds Light on Medical Device Reporting Requirements

Suzie Trigg, Michael Goodman and Neil Issar

Suzie Trigg

Michael Goodman

Neil Issar

In November 2016, the U.S. Food and Drug Administration ("FDA") issued a final guidance on medical device reporting for manufacturers ("Final MDR Guidance"). The Final MDR Guidance addresses: (1) manufacturers' reporting requirements; (2) written procedures, recordkeeping, and public disclosures; and (3) questions posed by industry and needed clarifications for manufacturers.

1. Manufacturers' Reporting Requirements

Manufacturers must submit reports of adverse events either: (a) no later than thirty days after becoming aware of a death, serious injury, or malfunction ("30-day report")[1]; or (b) no later than five days after becoming aware if either the reportable event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or the FDA has made a written request for a report. The Final MDR Guidance answers questions such as: Who is considered a manufacturer? What does "becoming aware" mean? What constitutes a "serious injury?" What constitutes a "malfunction?" What is "remedial action?" What must be included in the reports?

a. Serious Injuries

The definition of a "serious injury" has not changed since the FDA's guidance on medical device reporting in 1997: a "serious injury" is an injury or illness that (1) is life-threatening; (2) results in permanent impairment or damage to a body function or structure; or (3) requires medical or surgical intervention to preclude permanent impairment. But the agency recognized that it may be difficult to define "medical or surgical intervention." So, the Final MDR Guidance suggests manufacturers make a case-specific assessment of the risk to the patient without the intervention to determine if an injury or illness requires reporting.

b. Malfunctions: Two-Year Presumption Language

The Final MDR Guidance returns to the 1997 guidance's concept of a "two-year presumption" of recurrence following a malfunction, which had been removed in the 2013 draft. Specifically, once a malfunction has caused or contributed to a death or serious injury, there is a presumption that the malfunction is likely to recur and cause or contribute to a death or serious injury. This presumption continues until either there have been no additional deaths or serious injuries for two years or the manufacturer can show through verifiable data that the likelihood of another death or serious injury as a result of the malfunction is remote.

Regardless, the FDA strongly suggests that a manufacturer submit a notice of intent to cease reporting along with a summary of all data points collected over a two-year period. The agency will likely agree to the cessation of reporting if the data shows that the malfunction *cannot* recur beyond the two years. And the agency leaves the door open for a manufacturer to make a similar showing earlier than two years following an adverse event.

The Final MDR Guidance also eliminates the requirement for a trend analysis to be included in the reporting. But a manufacturer still must conduct a complete investigation on all product complaints. So, a trend analysis should be a routine activity performed and maintained as part of a comprehensive quality plan established at the manufacturer's facility. It is still advisable that adverse trends discovered as part of any investigation be mitigated through a Corrective and Preventive Action program.

c. User Errors

Similar to past guidance documents, the Final MDR Guidance defines a "user error" as a device-related error or mistake made by the person using the device. The FDA does not distinguish between deliberate acts and inadvertent acts. Further, the agency believes that user errors often reflect flaws in the device, user interface, or labeling. So, user errors that result in a serious injury should be reported to the agency like other adverse events. If an investigation reveals, however, that the injury was *solely caused* by user error with no device performance or labeling issues, the manufacturer is not required to file a report. The FDA strongly

UPCOMING EVENTS

Houston Provider Conference

Latest Trends and Developments in the Healthcare Sector

Kenya Woodruff
Chris Beinecke

February 23, 2017
Houston, Texas

ABA 18th Annual Emerging Issues in Healthcare Law

Living Between Fee for Service- & Value-Based Purchasing

Kenya Woodruff

March 8-11, 2017
New Orleans, Louisiana

recommends that the investigation and all supporting information be retained in easily accessible files.

2. Written Procedures, Recordkeeping, and Public Disclosures

The Final MDR Guidance outlines manufacturers' requirements for developing, maintaining, and implementing written reporting procedures; requirements for establishing and maintaining report files and records; and what information in manufacturers' files is subject to public disclosure.

The Final MDR Guidance also addresses concerns regarding duplicative reporting. All manufacturers of legally marketed medical devices in the United States, including foreign manufacturers who export devices to the United States, are subject to the MDR regulations and must submit required reports. This includes specifications developers (entities that do not manufacture but instead develop specifications for a device distributed under their name). Specifications developers also may arrange for the manufacture of devices labeled with another entity's name by a contract manufacturer. The draft guidance imposed reporting requirements for adverse events on both contract manufacturers and developers, eliciting numerous concerns regarding a redundancy in reporting.

The Final MDR Guidance limits the applicability of reporting requirements to specifications developers and *only* those contract manufacturers that actually market and distribute a medical device. Contract manufacturers that do not market or distribute the product are *not* required to file reports with the FDA. This should appropriately ease the reporting burden on entities that are merely serving as production factories for devices that bear another entity's name. But note that if both a contract manufacturer and the specifications developer market and distribute the device, then *both entities* must file medical device reports.

Many of the comments to the draft guidance suggested that filing responsibility should be determined contractually between the two entities. Though not entirely eliminating double submissions, the Final MDR Guidance encourages both entities to submit a joint request for a reporting exemption that specifies which entity will submit reports (though both should continue to maintain documentation about adverse events). The entity exempted from reporting still may be responsible for ensuring that reports are properly filed. If reports are not submitted by the non-exempt entity, the exemption will be revoked, and both entities will be required to submit.

3. Specific Issues and Situations

The Final MDR Guidance answers several questions posed by industry and clarifies manufacturers' obligations in specific scenarios:

- A delay in surgery alone, without any adverse impact on the patient, is not considered a reportable event. But if a malfunction or device failure causes the delay in surgery and it would be likely to cause or contribute to a death or serious injury if it recurred, then it is reportable.

- Manufacturers must maintain MDR files for two years from the date of an event or a period equivalent to the expected life of the device, whichever is greater. The "expected life of a device" is the time that a device is expected to remain functional after it is placed into use. This is not the same as a device's warranty period, or, for devices that require regular maintenance, the time between calibrations or maintenance cycles. Instead, it is a device's overall life.

- Including the risks and complications associated with the use of a device on the device's label does not exempt the manufacturer from reporting adverse events.

- Injuries caused by an approved medical device that is also under an Investigation Device Exemption ("IDE") for another use must be reported under *both* the MDR regulations and the IDE regulations.

The FDA will accept written or electronic comments on the Final MDR Guidance at any time.

[1] The Food and Drug Administration Amendments Act of 2007 modified malfunction reporting requirements such that manufacturers are only required to submit a quarterly summary of data points for all medical devices (with the exception of Class III and life-supporting, life-sustaining, or permanently implantable Class II devices). Note, however, that this does not change manufacturers' obligation to submit 30-day reports per MDR regulations.

An Update on Telemedicine in Texas and Beyond

Michelle "Missy" D. Apodaca and Neil Issar

Michelle "Missy" D. Apodaca

Neil Issar

The holding pattern for the telemedicine/telehealth industry (referred to generally in this article as "telemedicine") appears to be lifted with a stay in the Texas Medical Board ("TMB") vs. Teladoc litigation and the convening of the Texas Legislature in January. As published in the September *Health Law Vitals*, regulatory and legislative changes were on the horizon, and the next six months will be critical for telemedicine supporters to convince the Texas Legislature that further utilization of telemedicine will positively impact access to care and workforce shortage issues.

Update on TMB vs. Teladoc

Over the past five years, as the TMB amended various regulations and hindered companies providing medical services via telecommunications, Teladoc—a Dallas-based provider of telemedicine services offering access to physicians by phone and online video consultations—repeatedly clashed with the TMB. In January 2015, the TMB passed an emergency measure to prohibit the prescribing of drugs without an initial in-person visit. Teladoc filed a federal antitrust suit and obtained a preliminary injunction to prevent the measure from taking effect.[1] In turn, the TMB engaged in formal rulemaking and revised the rule to require a face-to-face or in-person evaluation to establish a defined physician-patient relationship.[2] The TMB claimed the rule struck a necessary balance between patient safety and the use of advanced technology, while Teladoc characterized it as limiting access and reducing patient choice. Teladoc filed suit again in April 2015 and obtained a second injunction to prevent the new rule from taking effect.[3]

The district court denied the TMB's motion to dismiss, holding that the TMB's rules are not protected state action because Texas does not actively supervise the Board's conduct.[4] The TMB initially appealed to the Fifth Circuit, but, in the wake of several amicus briefs supporting Teladoc's position (including a joint brief by the Department of Justice and the Federal Trade Commission), voluntarily withdrew its appeal in October 2016. The parties then jointly requested—and received—a stay in the litigation. The timing of the stay happens to occur while the Texas Legislature is meeting, which allows a legislative solution for the dispute. The case is set to resume on April 19, 2017, but the voluntary withdrawal and request for a stay may indicate an impending settlement that allows Teladoc to stay in business. This may be especially true as key critics of Teladoc's services have recently left the Board, and Governor Greg Abbott appointed six new TMB members with terms set to expire in 2021.

Texas Legislative Solution

The Teladoc-TMB conflict and other advances in health care technology spurred a number of stakeholders,

including the Texas Medical Association ("TMA"), University of Texas, Texas Association of Health Plans ("TAHP"), Texas Hospital Association, and Texas Academy of Family Physicians, to develop draft legislation prior to the convening of the 85th Texas Legislature.

Some of the stakeholders proposed a bill that redefines telemedicine to mean any health care service requiring "the use of advanced telecommunications technology, other than telephone or facsimile technology," including "video, audio, or data transmission." The proposed bill permits providers to use "store-and-forward" techniques, which would allow electronic transmission of clinical data (such as test results or diagnostic images) to another provider for review at a later time. Perhaps most importantly, the proposed bill would allow physicians to establish relationships with patients using any synchronous audio-visual or asynchronous store-and-forward technology, so long as it did not rely exclusively on audio-only communication, telephone calls, instant messaging, faxes, or internet questionnaires or consultations. This would address the crux of the Teladoc-TMB conflict: under the proposed legislation, Teladoc's online video consultations would constitute the formation of a physician-patient relationship. Details of other legislative fixes and policy changes proposed over the past year can be found **here**.

Currently, only two telemedicine-related bills have been filed for the 85th Legislative Session:

- H.B. 727: Relating to the use of home telemonitoring services under Medicaid, and
- S.B. 52: Relating to the reimbursement of providers for the provision of certain home telemonitoring services under Medicaid.

Neither bill proposes the sweeping reforms advocated by the stakeholders, but Senator Charles Schwertner recently met with many of them to discuss reform of current telemedicine laws and regulations. Thereafter, TMA and others provided Senator Schwertner with their concerns and recommendations for proposed legislation, including allowing providers to charge for telemedicine services and requiring payers to adopt transparent policies regarding reimbursement for such services. Meanwhile, TAHP has expressed concerns that expanding the current telemedicine coverage mandate would be "a far-reaching action taken without any insight into its actual impact on Texas consumers or the affordability of coverage."[5] Senator Schwertner will likely file a bill that fosters technological innovation to improve access to care without creating costly mandates that interfere with private market competition. The deadline to file bills and joint resolutions for consideration during the current legislative session is March 10, 2017.

Even without accounting for the potential effect of new legislation, the state's Health and Human Services Commission ("HHSC") reports steady growth in both client utilization of, and provider expenditures for, telemedicine, telehealth, and home telemonitoring services. From 2014 to 2015, client utilization increased 31% (from 22,433 to 29,407); provider participation increased 64% (from 280 to 459); and Medicaid spending on those services increased 63% (from $3.7 million to $6.1 million).[6] While the Legislature considers changes to the telemedicine laws and regulations, advocates also will be recommending changes to Medicaid policies.

Texas is not the only state with a shifting telemedicine landscape. In 2016, 44 states introduced over 150 telemedicine-related pieces of legislation addressing issues ranging from licensing and reimbursement to delivery standards. As Texas and other states continue to respond to the growing utilization of technology in the delivery of health care, lawmakers will almost certainly continue to adopt and amend state laws and regulations with an eye towards telemedicine.

Recently Enacted Federal Laws Promote Telemedicine

While Texas courts continue to tackle foundational issues, such as whether a video or telephone consultation establishes a physician-patient relationship, recently enacted federal laws further embrace the use of technology for the delivery of medical care. For example, the 21st Century Cures Act directs the Centers for Medicare & Medicaid Services ("CMS") to identify:

1) The populations of Medicare beneficiaries whose care may be improved by the expansion of telehealth services currently reimbursed by CMS;

2) Demonstration projects, models, and initiatives being conducted by the Center for Medicare and Medicaid Innovation that examine the use of telehealth services;

3) The types of high-volume services and diagnoses that may be furnished using telehealth; and

4) The possible barriers that prevent the expansion of telehealth services.[7]

Similarly, the Expanding Capacity for Health Outcomes ("ECHO") Act mandates research into the role technology can play in promoting the sharing of knowledge and collaboration between rural and urban centers.[8] The ECHO Act is intended to both increase access to patients in underserved areas and link specialists with primary care providers in those areas via interactive videoconferencing. There are over 6,000 primary care Health Professional Shortage Areas ("HPSAs")—populations or geographic areas with population-to-provider ratios of less than 3,500-to-1 (or 3,000-to-1 if there are unusually high needs in the community)—with a combined population of over 60 million people.[9] Alleviating shortages in all HPSAs would require more than 8,000 additional primary care physicians.[10] Increasing access to, and expanding the use of, telemedicine services may be the only tenable solution to addressing the shortage.

The Joint Commission Flip-Flops on Texting Ban

In 2011, The Joint Commission, a non-profit health care accreditation organization that accredits over 4,000 hospitals, stated that safety and security concerns bar providers from texting orders for patient care, treatment, or services. Then in May 2016, the Commission concluded that texting platforms had evolved enough to address safety, security, and retention concerns, even though the health care industry remains one of the most common targets of cyber-attacks. So, providers could transmit medical orders by text message provided that a secure text messaging platform was implemented that included a secure sign-on process, message encryption, delivery and read receipts, date and time stamps, customized message retention time frames, and specified contact lists for individuals authorized to receive and record orders.[11] The Commission's position was supported by studies that showed communication via secure text messaging could improve patient outcomes, reduce hospital stay lengths, and enhance care team efficiency.[12]

Yet only two months after The Joint Commission lifted its ban on text messaging, the organization placed a hold on its May 2016 decision. It decided to collaborate with CMS to produce guidelines to facilitate the implementation of secure texting of medical orders.[13] The Joint Commission reversed course entirely in December 2016 and again banned the use of secure text orders. Further, the Commission and CMS released the following recommendations:

- All health care organizations should have policies prohibiting the use of unsecured text messaging—that is, short message service ("SMS") text messaging from a personal mobile device—for communicating protected health information.

- Computerized provider order entry ("CPOE") should be the preferred method for submitting orders as it allows providers to directly enter orders into the electronic health record.

- In the event that a CPOE or written order cannot be submitted, a verbal order is acceptable; the use of secure text orders is not permitted at this time.[14]

In particular, The Joint Commission expressed concern that orders conveyed via text message could not be entered into patients' medical records in real time. Instead, an additional mechanism to transmit orders could lead to an increased burden on providers to manually transcribe text orders into the record or to contact the ordering clinician for any necessary discussion prior to order entry. So, while the advancement of communications technology might have addressed data privacy and security issues, there remain concerns that the delayed receipt of clinically urgent or time-sensitive texted health information could harm patients.

[1] *See* Teladoc, Inc. v. Tex. Med. Bd., No. D-1-GN-15-000238 (53rd Dist. Ct., Travis County, Tex. Feb. 6, 2015).

[2] *See* 22 TEX. ADMIN. CODE §§ 174.8(a), 190.8(1)(L).

[3] *See* Teladoc, Inc. v. Tex. Med. Bd., 112 F. Supp. 3d 529 (W.D. Tex. 2015).

[4] *See* Teladoc, Inc. v. Tex. Med. Bd., No. 1-15-CV-343 RP, 2015 U.S. Dist. LEXIS 166754 (W.D. Tex. Dec. 14, 2015).

[5] Letter from Jamie Dudensing, CEO, Texas Association of Health Plans, to Charles Schwertner, Chair, Senate Health and Human Services (Jan. 19, 2017).

[6] Report, Health and Human Servs. Comm'n, Telemedicine, Telehealth, and Home Telemonitoring Services in Texas Medicaid (Dec. 2016)

[7] Pub. L. No. 114-255, 130 Stat. 1033 (Dec. 13, 2016).

[8] Pub. L. No. 114-270, 130 Stat. 1395 (Dec. 14, 2016).

[9] Mark. W. Friedberg et al., Evaluation of Policy Options for Increasing the Availability of Primary Care Services in Rural Washington State 3 (2016)

[10] U.S. Dep't of Health & Human Servs., Health Resources & Servs. Admin. Data Warehouse

[11] The Joint Comm'n, Update: Texting Orders, 36 JT. COMM. PERSPECT. 1, 15 (May 2016).

[12] *See, e.g.*, Mitesh S. Patel et al., *Change In Length of Stay and Readmissions among Hospitalized Medical Patients after Inpatient Medicine Service Adoption of Mobile Secure Text Messaging*, 31 J. GEN. INTERN. MED. 863 (2016).

[13] The Joint Comm'n, Delayed Implementation of Removing Ban on Secure Text Orders Until September 2016, 36 JT. COMM. PERSPECT. 1, 7 (July 2016).

[14] The Joint Comm'n, Clarification: Use of Secure Text Messaging for Patient Care Orders Is Not Acceptable, 36 JT. COMM. PERSPECT. 1, 9 (Dec. 2016).

FDA Issues Guidance on Lead in Lipsticks and Other Cosmetics

Suzie Trigg and Tiffany Ferris

Suzie Trigg

Tiffany Ferris

The U.S. Food and Drug Administration ("FDA") has issued Guidance recommending a maximum level of 10 parts per million (ppm) of lead in certain cosmetic products. The guidance is for lip products—lipstick, lip gloss, and lip liners—as well as externally applied cosmetics like eye shadows, blushes, shampoos, and body lotions.

Lead is often present in cosmetics, as it is an element in many color additives. In large enough concentrations, lead can pose health risks. Lead can be absorbed through the skin and, in the case of lip products, through ingestion. The FDA has concluded that use of cosmetic products with less than 10 ppm of lead would not pose a health risk to consumers.

The FDA's recent Guidance follows studies of lead levels in both cosmetic lip products and externally applied cosmetics, which found that these products generally contain less than 10 ppm lead. Thus, the FDA concludes that this maximum level is readily achievable through appropriate sourcing and good manufacturing practices. Moreover, the International Cooperation on Cosmetics Regulation has adopted the same standard, again indicating to the FDA the feasibility of its proposed ceiling limit on lead.

The FDA is accepting comments until February 21, 2017.

Applying Blockchain Tech to Medical Records for Improved Security and Access

Neil Issar

Neil Issar

The technology that forms the foundation for digital currencies like Bitcoin could be the technology that provides unprecedented security for and access to medical records.

The Blockchain

For years, online communities sought increased freedom and autonomy by shielding their economic activities from the government and corporate intermediaries. The problem, however, was how to quickly and securely exchange money, goods, or services online between unfamiliar—and potentially anonymous or even malicious—parties without a central marketplace operator (such as eBay or PayPal) to facilitate the exchange. The solution came in the form of cryptocurrencies—currencies that rely on decentralization and encryption (or cryptography), rather than a central intermediary such as a bank or government authority, to provide transparency and security.

Cryptocurrencies like Bitcoin are based on a technology called the blockchain, which, as the name implies, is simply a chain of "blocks." Each block contains the data of all transactions within a period of time and a reference to the block before it. In other words, the blockchain is the cryptocurrency's *public* ledger of past transactions. This differs from most e-commerce systems which typically maintain a centralized *private* ledger of all transactions. Since anyone can access the blockchain to verify or compile a list of every single exchange, anonymous strangers can trust each other while using Bitcoins to make transactions despite the lack of a supervisory or controlling authority.

More importantly, the blockchain is secure and practically tamper-proof since each transaction is uniquely time-stamped and converted into an alphanumeric value (called a "hash") that is replicated across the entire network. Alterations to existing hashes would need to occur at every node of the network to be accepted by the system. This makes data stored on the blockchain extremely resistant to external modification such as hacking.

Bitcoin and other cryptocurrencies have been marked by value volatility and association with illicit activities. While some remain wary of Bitcoin's checkered past, the underlying blockchain technology is increasingly accepted as having applications far beyond digital value exchange. This is especially true given the nearly endless list of activities that require some form of reliable transaction verification or a secure repository of information. Blockchain technology allows individuals to engage in such activities at greater speed, lower cost, and without having to rely on a central authority.

Factom and Medical Records

The healthcare industry is particularly sensitive to privacy concerns yet alarmingly susceptible to data breaches. In 2016, there were 324 reported breaches of unsecured protected health information ranging in size from 500 to over 3.6 million affected individuals. So, unsurprisingly, various startup companies are attempting to apply blockchain technology to medical recordkeeping. For example, the Bill and Melinda Gates Foundation recently awarded a grant to Factom, a blockchain technology firm based in Austin, Texas, to fund the creation of an electronic health records system that provides immutability and security in an affordable manner.

Factom distills collections of data into a single hash and then adds them to the Bitcoin blockchain. This allows the Factom framework to store vast amounts of information without slowing down the blockchain network. With medical records, the hash would serve as a fingerprint of the data for time-stamping and verification purposes. In other words, Factom

serves as a mathematically provable auditing and notarization service.

The content of the records themselves would not be revealed to third parties or transferred from their original digital location. So, Factom-secured records likely would not contravene the privacy provisions of the Health Insurance Portability and Accountability Act of 1996. In fact, both the National Institutes of Standards and Technology and Department of Health & Human Services permit the de-identification of protected information by one-way conversion to hash values if certain requirements are met.[1] Factom's blockchain also will allow providers to keep pace with the big data revolution impacting the healthcare industry.

The Bill and Melinda Gates Foundation specifically envisions Factom-secured records benefiting developing nations in which paper-based medical records or information stored on local servers are often compromised by geopolitical instability. Technology that relies on distribution and decentralization is well-suited to maintain the privacy and security of medical records in an affordable and practical way, even in environments with poor web connectivity.

For example, Factom could digitize, store, and encrypt a hospital's medical records in a decentralized fashion. Access to these records would not be dependent on a strong internet connection to a central server or database, which may be particularly unreliable in a destabilized region, since the data would be distributed across various nodes of the blockchain network. Medical providers and patients would then be able to access and share documents such as vaccination records and HIV viral load measurements on their phones to ensure they are providing or receiving the correct treatment. And because the records are being accessed via the blockchain, they can be easily tracked and authenticated as accurate and unchanged. Factom also plans to use biometric verification for an added layer of security. It is easy to imagine Factom moving medical recordkeeping from a fragmented, primarily manual process to a digital, automated, and secure framework.

Future Applications of Factom's Blockchain Tech

The advantages of Factom's blockchain technology—namely, time-stamping, immutability, and secure, decentralized storage of large sets of data—could be embraced by other facets of healthcare such as telemedicine and the pharmaceutical supply chain.

The Centers for Medicare & Medicaid Services recently amended federal regulations to include the use of "telemedicine, e-visits, and/or other evolving and innovative technological solutions" as criteria that states should consider when determining network adequacy standards. 42 C.F.R. § 438.68(c)(1)(ix). The application of blockchain technology to medical recordkeeping is a clear example of an evolving and innovative technological solution and soon could be viewed as another criterion for consideration. But this means projects by companies like Factom could raise conventional telemedicine issues regarding establishment of the physician-patient relationship, licensure, and reimbursement. Alternatively, Factom's work may supplement traditional forms of telemedicine by automating and improving certain aspects, such as identity authentication and insurance verification.

Similar supplementation by blockchain technology could improve pharmaceutical distribution. The Drug Supply Chain Security Act of 2013 outlined a ten-year plan to build an electronic, interoperable system to identify and track drugs through all phases of distribution. The statute imposes a large documentary burden on drug manufacturers, distributors, dispensers, and repackagers by requiring the capture and sharing of product tracing

and transaction information. But using blockchain technology to secure and verify this information, as Factom envisions with medical records, could introduce unprecedented visibility and transparency to the pharmaceutical industry. The technology could equally benefit electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients.

Applying blockchain technology to electronic health records, telemedicine, and drug distribution and monitoring will impact both the need for, and practice of, intermediaries such as lawyers. At the same time, the technology offers a great opportunity for firms and corporations willing to innovate, particularly in regions in which central databases and government infrastructure are unreliable. Entities that adapt and embrace blockchain technology may be able to provide more efficient and higher quality services.

[1] *See* Dep't of Health & Human Servs., Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (Nov. 26, 2012).

2016 FDA Year in Review: Food Edition

Suzie Trigg and Priscilla Bowens, DVM, MPH

Suzie Trigg

Priscilla Bowens

As the food industry prepares for a new year, we take a look back at the major developments of the past year. The U.S. Food and Drug Administration ("FDA") released three final rules related to the implementation of the Food Safety Modernization Act of 2011 ("FSMA"), completing the list of the seven foundational rules (other than registration amendments) initially proposed in 2013 and 2014. The FDA also published much-anticipated final rules on changes in serving size and nutrition facts and on supplements labeling, as well as guidance on menu labeling. Here, we provide a brief overview of these final rules and discuss implications for food companies, retail establishments, and their affiliates.

Food Safety Modernization Act

Sanitary Transportation of Human and Animal Food

The FDA released its final rule on the Sanitary Transportation of Human and Animal Food in April 2016. As part of the FDA's effort to "focus on the prevention of food safety problems throughout the food chain," the rule covers transportation operations for food not completely enclosed by a container. Shippers, loaders, carriers, and receivers engaged in food transportation operations must update or establish requirements for record keeping, training, vehicles and transportation equipment, and transportation operations. However, food shipped through the United States to another country or stored in the United States for later export is not subject to the rule. As an important component of FSMA implementation, food companies should make it a priority to establish or implement policies and procedures to comply with the new rule. Small businesses have two years to comply, whereas other businesses (*i.e.*, not small or otherwise exempt) must comply one year from the date of the rule's publication, which means April 2017.

Mitigation strategies to protect food against intentional adulteration

Effective July 2016, the FDA's final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration requires certain domestic and foreign food facilities to prepare a food defense plan to mitigate and respond to internal and external threats that have the potential to cause widespread public health harm.

The rule addresses intentional adulteration in the context of manufacturing facilities, raw agricultural commodities (*i.e.*, fruits and vegetables), and high-risk foods that pose a serious threat to public health. However, farms (other than farms that produce milk) are exempt from the requirement in the context of high-risk foods. While the rule provides several additional exemptions aimed at very small businesses (*i.e.*, companies with less than $10 million in sales over three years) and low-risk production practices, over 3,400 firms (*i.e.*, large companies) that operate 9,800 food facilities are covered under the rule.

Although generally exempt, very small businesses have five years to comply with the rule, while small and other businesses must comply within four years and three years, respectively. For those companies covered under the rule, the food defense plan must assess vulnerabilities for each step in a facility's process and manage its mitigation strategy through monitoring, corrective actions, and verification. Personnel training and recordkeeping are also required and help to reinforce the establishment and implementation of mitigation strategies.

Amendments to registration of food facilities

Rounding out its implementation of FSMA, the FDA amended its requirements for facility registration in July 2016. Among those requirements, domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States must (1) renew their registration every two years, between October 1 and December 31 of each even numbered year; (2) maintain an email address; and (3) attest in writing that the FDA will have access to inspect their facility according to the applicable sections of the Federal Food, Drug, and Cosmetic Act. Mandatory electronic registration will be delayed until January 4, 2020. Registrations must also contain the type of activity conducted at the facility.

In addition to the above final rules, the FDA is also extending compliance dates for (1) Calorie Labeling of Articles of Food in Vending Machines; (2) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; (3) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; (4) Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; and (5) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

Labeling and Nutrition

Menu Labeling

With the final guidance published in April 2016, the Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments continues to create an impact on the restaurant industry. The rule's requirements affect restaurants and similar retail establishments with 20 or more locations, doing business under the same name, that sell substantially the same menu items and sell restaurant-type foods ("covered establishments"). Covered establishments must comply by May 5, 2017.

As compliance and enforcement looms closer, covered establishments have moved towards changing their menus in accordance with the rule. Those changes include: (1) the prominent display of calorie numbers of standard menu items on menus or menu boards; (2) signage displaying calorie numbers of standard menu items adjacent to food on display or self-service food; and (3) additional written nutritional information upon consumer request. The FDA has also made clear that covered establishments must have a "reasonable basis" to determine values for calorie or other nutrition claims provided for standard menu items. Reasonable basis can be determined through a number of

means including: (a) calculations; (b) values listed in cookbooks; (c) laboratory analysis of menu items; or (d) other reasonable means.

Updated Nutrition and Supplement Facts Labels

After more than twenty years, the FDA published a final rule in May 2016 updating the nutrition and supplement facts label in an effort to help consumers make more informed decisions about what they eat. The new label, debuting in July 2018 for manufacturers with more than $10 million in annual food sales and a year later for those with less than $10 million in annual sales, features a refreshed design and a revised breakdown of caloric intake. Notably, type size has increased for "Calories," "servings per container," and "Serving size" declarations. "Sugars" will change to "Total Sugars" and include new information on "Added Sugars" because scientific data shows a correlation between the total daily consumption of 10 percent or more of added sugars and difficulties in meeting dietary goals. There are also changes in required vitamin information: vitamin D and potassium levels are required on the label, whereas vitamins A and C are permitted, but not necessary.

Changes to serving sizes of common foods

Serving sizes also received a significant update. According to the FDA, data suggests what is commonly known: as food consumption increased over the past few decades, so did the typical serving size, and current labels must reflect that change. Specifically, foods that are generally consumed in one sitting (*e.g.*, soda and a pint of ice cream) must be labeled with nutrition facts for one serving, not for two or more servings. Manufacturers must also provide dual columns on larger packages that can be consumed in one or more sittings so consumers can easily understand how much they are actually eating.

It will take years of data collection and analysis to provide the FDA, consumers, and food companies with much needed information on whether changes to serving size information can help reduce the risk of chronic diseases while increasing healthy dietary patterns.

OIG Advisory Opinions – Calendar Year 2016

Kenya S. Woodruff and Neil Issar

Kenya S. Woodruff

Neil Issar

The U.S. Department of Health & Human Services ("HHS") Office of Inspector General ("OIG") issues advisory opinions to provide guidance on the application of the Anti-Kickback Statute ("AKS") and other OIG sanction statutes to existing or proposed business arrangements. An OIG advisory opinion is legally binding on the HHS and the requesting party or parties; it is not binding on any other governmental department or agency. Although other parties may look to these opinions for guidance, only the party that receives a favorable advisory opinion is protected from OIG administrative sanctions and only so long as the arrangement is conducted in accordance with the facts submitted to OIG at the outset.

In 2016, OIG issued thirteen new advisory opinions and modified or terminated six previously issued opinions. The new opinions dealt with various topics, including:

- Preferred hospital arrangements involving discounts on inpatient deductibles and premium credits;
- A group purchasing organization (GPO) arrangement in which the GPO would be wholly owned by an entity that also wholly owns participants in the GPO;

- An academic medical center offering pregnant women transportation aid to and from the hospital for delivery and short-term lodging;
- Supplemental payments from a hospice to nursing facilities for dually eligible hospice patients;
- Computerized point-of-care vaccine storage and dispensing systems located in physicians' offices;
- Joint funding of a transportation coordinator to educate patients about local transportation options and subsidize certain forms of transportation for financially needy patients;
- A laboratory's provision of free tube- and container-labeling services to dialysis facilities; and
- Waiver of patients' cost-sharing obligations and additional compensation for participation in a government-funded clinical research study.

To read detailed summaries of each opinion, click on the PDF linked below.

Detailed-Summaries-of-OIG-Advisory-Opinions.PDF

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

KENYA WOODRUFF
PARTNER | CHAIR -
HEALTHCARE PRACTICE GROUP
kenya.woodruff@haynesboone.com