

THE NEWSLETTER FROM THE BDO CENTER FOR HEALTHCARE EXCELLENCE & INNOVATION

BDO KNOWS HEALTHCARE



CURES ACT PROVIDES WORLD OF OPPORTUNITY FOR HEALTHCARE INNOVATION BUT REQUIRES PROVIDERS TO READ THE FINE PRINT TO MITIGATE COMPLIANCE RISK

By Venson Wallin

On Dec. 13, President Obama signed the 21st Century Cures Act (the Cures Act) into law, boosting healthcare research dollars, streamlining the Food and Drug Administration (FDA)'s drug and medical device approvals processes, and advancing mental health and addiction treatments.

The move followed a bipartisan congressional sweep in which the [Senate approved the bill 94 to 5](#) and the [House 344 to 77](#).

DETAILS

First, incorporating input from providers, patients and researchers, [the Cures Act](#) provides the National Institutes for Health (NIH) with \$4.8 billion in funding over 10 years. This includes \$1.5 billion earmarked for research into genetic, lifestyle and environmental diseases, \$1.8 billion earmarked to accelerate cancer research through Vice President Joe Biden's Cancer Moonshot initiative, and \$1.5 billion earmarked to combat brain diseases like Alzheimer's and epilepsy. The \$4.8 million also includes funds for the Precision Medicine Initiative, an effort to use big data

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in collaboration with physicians to create more efficient, personalized treatments.

Second, the law provides the FDA with \$500 million to streamline regulations to move drugs and medical devices through approvals more quickly. It also contains provisions to allow the department to:

- ▶ Modernize clinical trials and the ways safety and efficacy data is analyzed;
- ▶ Streamline regulations so the process for securing approvals on medical devices, technologies, vaccines and regenerative medicine therapies is more efficient;
- ▶ Create incentives to develop both drugs for pediatric diseases and medical countermeasures; and
- ▶ Provide the FDA with greater flexibility in reviewing and approving medical devices if they provide first-of-a-kind technologies.

Third, the law provides resources aimed at improving the interoperability of electronic health record (EHR) systems, and improving providers' education on the latest medical technologies.

Next, the law includes \$1 billion in grants to help states combat the growing opioid crisis and improve mental health treatment. Based on the Helping Families in Mental Health Crisis Act, this provision also:

- ▶ Creates a new assistant secretary for mental health and substance abuse at the Substance Abuse and Mental Health Services Administration (SAMHSA) to coordinate mental health programs at the federal level;
- ▶ Instructs the secretary of Health and Human Services (HHS) to clarify when communication is allowed under HIPAA so that communication between providers, patients and families is

coordinated to boost mental health treatment; and

- ▶ Expands [Assisted Outpatient Treatment](#), a court-supervised treatment for children or adults with a history of repeated hospitalizations.

Finally, the law requires the [HHS to create and maintain a centralized database of terminated Medicaid providers](#) in any state—a component aimed at combatting fraud, a risk increasingly on the minds of providers as the transition to value-based reimbursement continues.

Previously, providers entered agreements directly with the respective states as there was no centralized, federal database. Under the new law, by July 2018, states will be required to submit information about providers terminated from their Medicaid programs, whether for fraud or other criminal offenses.

INSIGHTS

The law underlines the government's focus on expediting the development of cures for serious diseases that are not only devastating to patients, but also add up to a significant share of the total cost of healthcare nationally. (In 2016, Alzheimer's and other dementias alone are forecast to cost the country [\\$236 billion](#).)

It also warrants special attention where compliance is concerned, and providers should closely monitor and address certain components more than others. These include:

The centralized database of providers terminated by Medicaid. The transition to value-based care, which encourages the collaboration of providers across the care continuum to boost care efficiencies, creates an increased risk for Medicaid fraud. Providers, particularly those that work with post-acute care and home health providers, should pay special attention to this component and use the database to

ensure their provider partners have not previously been convicted of fraud. While many organizations have procedures in place to check state databases for excluded providers within their state of operations, the ability to identify those excluded providers from other states who have recently moved into their state of operations has always been a challenge. The new law addresses that by creating the national database; however, organizations must challenge their existing procedures to ensure any additional steps related to the national database are incorporated into their routine credentialing process, including acknowledgment that the national database has been consulted for any new providers. Additionally, once the database is active, organizations should implement the best practice of reviewing existing providers to ensure Medicaid has not excluded them in another state, which would expose the organization to potential liability or reimbursement denial.

Providers should also ensure their internal controls to mitigate fraud are up-to-date, improving them where necessary and disclosing any discrepancies before the database comes into effect. Those who don't may do so at their own peril as information about Medicaid fraud becomes more widely available.

Expedited FDA approvals. While this opens new (and quicker) avenues to secure drug and medical device approvals, and knocks down the regulatory obstacle to quicker medical innovation, it also presents greater risk for product discrepancies to slip through the cracks.

With new types of risk to medical devices stemming from cybersecurity and greater regulatory scrutiny under the False Claims Act, providers should put internal controls in place to adequately assess the quality of drugs and devices before prescribing them to patients. Because the law requires the FDA to consider real-world evidence in making approval decisions, providers should incorporate this data

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into their internal controls and choose their partners accordingly. The new law promotes innovation in the medical device area, and thus, the industry will see a significant increase in new vendors. While organizations should continue to pursue partnerships with vendors who can provide innovative ways to enhance patient treatment and satisfaction, they should do so with a healthy dose of cautious optimism. With a proliferation of new opportunities to expedite innovation, not all vendors will have appropriate policies, procedures and internal controls in place to ensure compliance with the CMS and state regulations, and, most importantly, patient safety. As organizations identify new innovative techniques and devices to pursue, a critical step in partnering with vendors should be to conduct due diligence around their approval processes for new products, their quality control management and their process for securing FDA approvals.

Goals that were once lofty could now be seemingly reachable under the Cures Act. While it provides opportunity for increased innovation and more cost-effective healthcare, providers should also take a closer look at their internal compliance controls—and address new risks because of this legislation.

By doing so providers can break new ground in innovation, while doing so in an orderly fashion.



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IoT IN HEALTHCARE PRESENTS OPPORTUNITY BUT ALSO PROMPTS HIGHER GUARDRAILS AROUND CYBERSECURITY, FALSE CLAIMS ACT

By Judy Selby and Patrick Pilch



The adoption of connected devices—the so-called Internet of Things (IoT)—in healthcare presents an important opportunity to dramatically improve the quality and efficiency of care for patients.

The market for healthcare IoT is booming, poised to reach [\\$177 billion](#) by 2020. With such great potential, however, come higher guardrails in the form of increased regulatory scrutiny in two key areas: cybersecurity and the False Claims Act (FCA).

FDA CYBERSECURITY GUIDANCE FOR MEDICAL DEVICES

In January 2016, the [FDA issued draft guidance](#) concerning the post-market

cybersecurity of medical devices, recognizing that vulnerabilities in those devices could present risks to patient safety and to the effectiveness of the devices. The guidance outlines several important pre-market considerations:

- ▶ Identifying assets, threats and vulnerabilities;
- ▶ Assessing the impact of threats and vulnerabilities on device functionality and patients;
- ▶ Assessing the likelihood of a threat and of exploits affecting devices;
- ▶ Determining risk levels and outlining effective mitigation strategies; and
- ▶ Assessing residual risk and risk acceptance criteria.

The guidance also addresses key post-market considerations to mitigate vulnerabilities that could permit the unauthorized access, modification, misuse

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or denial of use, or unauthorized use of information accessible via the device:

- ▶ Monitoring cybersecurity information sources for identification and detection of vulnerabilities and risks;
- ▶ Assessing and detecting the presence and impact of a vulnerability;
- ▶ Establishing and communicating protocols for vulnerability intake and action;
- ▶ Defining essential clinical performance to develop controls that protect, respond and recover from cybersecurity risk;
- ▶ Adopting a multidisciplinary vulnerability disclosure policy and practice; and
- ▶ Deploying controls that address cybersecurity before a vulnerability can be exploited.

REAL LIFE IMPACTS

The messy situations [St. Jude Medical and Johnson & Johnson find themselves in](#) should serve as warnings to the industry regarding the impact of cybersecurity concerns.

In a real-life claim that parallels television fiction, Muddy Waters Capital, an investor with a short position in St. Jude Medical, made accusations that the medical device company's pacemakers and defibrillators are vulnerable to cyber-attack. Muddy Waters claimed that St. Jude hadn't met certain conditions outlined in FDA guidance and would have to recall the vulnerable devices and submit the updated devices for new FDA approval. Those unproven allegations were costly for St. Jude. Stock prices took a dive, even before the FDA investigated the claims. (The FDA announced an investigation shortly thereafter, but noted in a statement that, based on information obtained to date, patients could continue using devices as directed by their physicians and that "the benefits of the devices far outweigh any potential cybersecurity vulnerabilities," as told by [Reuters](#).)

And in October, Johnson & Johnson made public a vulnerability in its insulin pumps that could theoretically be exploited by hackers. Although there had been no reported attacks on the pumps, the announcement made front-page news.

THE EVOLUTION OF THE FALSE CLAIMS ACT

In June 2016, in a highly anticipated decision, the [Supreme Court](#) widened the net for [whistleblowers in healthcare](#) by upholding the "implied false certification" theory of liability of the FCA, which sets out both to prevent defrauding the government and to penalize those who commit such fraud. The theory treats a Medicaid payment request as an "implied certification of compliance" with pertinent statutes, regulations or contract requirements—including those related to cybersecurity—*material* to conditions of payment. Notably, the Court clarified *material* broadly as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

The decision set a precedent for future false claims cases. What matters most now is not how a state or federal government labels relevant laws or requirements for payment, but whether the defendant knowingly violates a condition it knows to be *material* to the Medicaid payment decision. Failure to disclose such violations could leave healthcare organizations vulnerable to non-compliance with the FCA.

KEY TAKEAWAYS

Typical examples of false claims include improper billings, paying physicians for referrals or kickbacks, ghost patients, up-coding of services, and services not rendered but billed. But the expanse of the FCA has been considerable since its inception, with the recent Court decision and FDA guidance only speeding up that process.

Under the cybersecurity lens, if an organization bills for services rendered but the quality of those services is non-compliant with security requirements—or if it is aware of a potential vulnerability but fails to disclose it—the organization might be deemed non-compliant with the FCA. For an FDA-regulated medical device manufacturer, consequences could also include a costly device recall and having to resubmit the device for FDA approval.

Although the federal administration's new regulatory and cybersecurity policies are still developing, additional regulation would not be unexpected given the [relentless number of cyber-attacks](#) on healthcare organizations and their [potentially devastating impact](#).

In this environment, medical device manufacturers should carefully consider their potential exposure to liability under the FCA. Moreover, to the extent that a healthcare provider is responsible for the maintenance and upkeep of biomedical equipment, medical devices or, in cases, patient implantable devices—all of which are vulnerable to breaches—the provider could also be subject to the FCA.



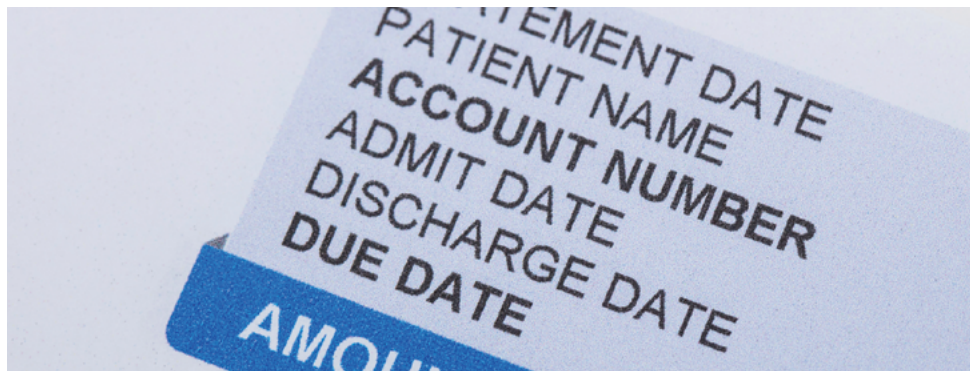
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AS HEALTHCARE FOCUSES ON FALSE CLAIMS LIABILITY, INDUSTRY SHOULD MIND THE GAAP

By Gerry Zack, Steven Shill and Nanda Gopal



Concern around fraud in healthcare is nothing new, especially since the Affordable Care Act was enacted, unleashing a revolution in the way care is reimbursed.

The [Department of Justice](#) intensified that concern this past June when it netted 301 individuals for \$900 million in false billing.

But when it comes to addressing the risk for fraud in healthcare—an industry under growing pressure and one ripe for fraudulent activity—organizations should pay attention to a risk increasingly on the minds of regulators: non-GAAP (Generally Accepted Accounting Principles) reporting measures.

The consistent use of an agreed-upon set of principles applied to the preparation of financial statements is key to objectively comparing companies or analyzing their results over time. In most jurisdictions around the world, these rules are known as the GAAP. For organizations concerned with sustaining [investor interest and confidence](#), reporting non-GAAP financial measures, like Earnings Before Interest, Tax, Depreciation and Amortization (EBITDA), can be useful to presenting a different context to the GAAP financial statements.

In fact, this is a growing approach.

For 18 out of 20 Dow Jones Industry companies that reported non-GAAP earnings per share (EPS) alongside GAAP figures in 2015, the non-GAAP figures were higher—on average by 30.7 percent, [one report](#) showed. In fiscal year 2014, the comparable difference between the two was just 11.8 percent.

And perhaps more strikingly, in 2015, just [5.7 percent of companies](#) in the S&P 500 Index closed their books exclusively using GAAP measures, compared to 25 percent in 2006.

Healthcare is one of the industries (along with the IT, materials and utilities sectors) where non-GAAP reporting is most common. And not surprisingly, as the diversity of both healthcare constituents and reporting requirements often makes it hard to use comparable GAAP terms to gauge the performance of organization A versus organization B. While permissible in their own right, there is subjectivity in the way non-GAAP measures are presented, and so there can be inconsistencies even though the components used to compute non-GAAP measures may have been obtained from audited financial statements. It's when these measures start taking a turn toward misleading—like by presenting a non-GAAP measure inconsistently between reporting periods, or providing undue prominence to non-GAAP measures or selective editing of

data—that they run the risk of violating securities laws.

INDUSTRY SHIFTS CAN MAKE AN INDUSTRY LOOK SHIFTY

Consolidation, restructuring and new business collaborations between non-traditional stakeholders are rampant in healthcare, impacting the very definitions of “core” business elements, and increasing the complexity of accounting.

Non-cash expenses and non-recurring charges: The consolidation environment in the healthcare industry is full of non-cash and one-time charges. Healthcare companies commonly exclude restructuring charges from non-GAAP measures, with about 65 percent of non-GAAP reporting entities in the industry doing so. This is an area of increasing concern as the industry continues to see unprecedented M&A and companies reorganize to remain profitable under new models.

According to GAAP, all costs associated with a business combination must be expensed by the acquirer. These include one-time charges like legal diligence fees, investment banker fees, financial diligence fees and commissions. While they don't technically recur, their impact can continue to weigh significantly on a business even after the reporting period; thus, their absence can be particularly misleading.

As an example, the acquisition of a not-for-profit hospital by a for-profit one dependent upon the assumption of the pay-down of a defined benefit pension plan liability that is slowly bleeding the acquiree to death is a perfect scenario for a healthcare organization to try to treat those costs as one-time restructuring or nonrecurring charges.

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MIND THE GAAP

Finally, in the area of non-cash charges, organizations often exclude impairment charges, such as those resulting from writing off goodwill from past acquisitions, from their non-GAAP metrics.

Defining core business elements: In the healthcare world, "core business" has become an expansive term. In a broader healthcare sense, "core" may no longer be limited to hospitals or provider services, but may also encompass payer responsibilities, as providers increasingly collaborate with insurers and take on capitated risk. Additionally, "core" may no longer be limited to acute care but also include post-acute care—potentially even including telehealth services. Healthcare companies must carefully define what does and does not fall into their core businesses as they face accounting scrutiny.

Use of pro formas in acquisitions:

Because for-profit companies and nonprofits construct their income statements differently, the acquisition of the latter by the former can raise problems of an interpretive nature when presenting non-GAAP metrics.

Value-based reimbursement

adjustments: Under value-based reimbursements, Medicare rewards providers with bonuses when they meet the target cost of care for particular services, but penalizes them with fines when they fail to meet the same target. This presents the potential for missteps if healthcare organizations use non-GAAP reporting to exclude these potential adjustments, even though they should be disclosed as operational costs. Further, as providers are held to outcome standards, the industry faces a potential demand for the development of "customized" metrics to show the financial impact of value-based care, especially since considerable questions remain over how to define and measure quality.

Other examples of misleading reporting practices include (1) publishing non-GAAP

DID YOU KNOW...



Fee-for-service revenues have continued to decline by more than 20 percent, with value-based payments rising proportionally, the *American Medical Group Association* revealed.

Privately-insured Americans spent almost 5 percent more on healthcare in 2015 compared to the previous year, according to data from the *Health Care Cost Institute*.

The Kaiser Family Foundation reports that 74 percent of U.S. residents say making high-cost prescription drugs for chronic conditions affordable should be the top healthcare priority.

Healthcare robot shipments will increase from about 3,400 units per year in 2016 to more than 10,500 units annually by 2021, according to *Tractica*.

Healthcare CFO total direct compensation is 33 percent of healthcare CEO compensation, on average—the greatest CEO/CFO pay discrepancy out of eight industries examined in *The BDO 600*.

measures more prominently than audited GAAP figures, running the risk that readers will mistakenly assign a higher level of credibility to the former; (2) leaving out a clear description of how a non-GAAP measure is calculated, along with the necessary reconciliation; and (3) using unreliable (and unaudited) non-GAAP reconciling items to calculate non-GAAP measures, like "underlying" net income and "from recurring operations."

The issue of non-GAAP measures has been on the minds of regulators for years, and in March 2016 the Securities and Exchange Commission (SEC) signaled broad change—and potential regulation—coming down the pike.

"It's something that we are really looking at—whether we need to rein that in a bit even by regulation," SEC Chair Mary Jo White said, as [reported](#) by *The Wall Street Journal*. "We have a lot of concern in that space." In May 2016, the SEC went a step further, releasing new [guidance](#) on the use of such measures.

Because of the diverse types of companies and reporting in healthcare, it's often difficult to use comparable GAAP measures

to gauge the performance of one type of healthcare entity (e.g. a hospital) versus another type (e.g. an insurer). Hence, there are legitimate reasons for including non-GAAP measures in healthcare reporting, particularly to provide additional insight into an organization's operations beyond what is included in the audited financial statements. But healthcare entities should do so cautiously—ensuring consistency with SEC guidance and rules—given the new regulatory focus on such measurements. Otherwise, they risk being liable under the anti-fraud provisions of securities laws and could find themselves the target of shareholder litigation.



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PErspective in HEALTHCARE

A FEATURE EXAMINING THE ROLL OF PRIVATE EQUITY IN THE HEALTHCARE INDUSTRY

THE SURGE OF THE GLOBAL HOME HEALTHCARE MARKET



The global home healthcare market is expected to be worth nearly \$350 billion

by 2020, up from \$227.5 billion in 2015 and representing a 9 percent compound annual growth rate over five years, according to research firm MarketsandMarkets.

A number of factors are driving this growth, including ageing populations, an increase in the prevalence of chronic illness, advancements in healthcare technology and devices, and the increasing need for—and regulatory requirement to seek—cost-effective healthcare delivery to limit spiraling costs.

The market is extremely fragmented, with several large players steadily growing their market share. According to the U.S. Census Bureau, in 2002, the 20 largest home health firms controlled approximately 16 percent of the market. By 2012, that number had risen to around 21 percent. Beyond these firms, the market includes many individual centers and a growing number of franchises, such as Right at Home and SYNERGY HomeCare. According to a recent *Forbes* article, the number of home healthcare franchises has risen from 13 companies in 2000 to 56 today, and the growing demand for home healthcare services, coupled with high potential revenues and the potential for international expansion, makes them attractive investment targets.

Shifting reimbursements particularly in the context of bundled payments are set to increase investor interest in the sector. The

Centers for Medicare and Medicaid Services (CMS)'s recent introduction of bundled payments in both joint replacement and cardiac care—aimed at driving down costs and improving provider accountability over patient outcomes—will likely have a big impact on competition in the home healthcare field. Both CMS bundles include waivers for home health and telehealth services not previously covered. However, not all home health providers are equal, and delivery of the quality of care needs to be measured and validated.

Commercial insurers tend to follow CMS' lead. While joint replacement patients tend to be older and covered by Medicare, cardiac patients skew younger. As commercial insurers expand their coverage of home health services to drive down overall treatment costs, home healthcare providers will have access to new demographics and have the opportunity to grow their market share.

In terms of impact on deal flow, after a relatively sluggish 2015, deal-making has been robust during 2016. Post-acute providers are looking to grow their home health and hospice services, and large, publicly traded players have grown increasingly active, according to *Home Health Care News*. The largest providers announced robust M&A pipelines at the beginning of the year: Amedisys said it planned to make 400 acquisitions, and LHC Group planned deals worth a total of almost \$1 billion. New regulations such as CMS' Pre-Claim Review Demonstration (PCRD) and a sudden drop in share prices in September have contributed to a slowdown in LHC's plans.

FUTURE PERSPECTIVES: WHAT'S NEXT FOR HEALTHCARE INVESTORS

Signs show that healthcare technology firms may benefit from Silicon Valley's desire to diversify away from B2C software vendors over fears the recent consumer tech bubble is about to pop—or that the unicorn-filled market will at least undergo a sustained correction. *CB Insights* reports that 80 technology firms have accepted lower valuations to raise additional funding since 2015, and *Bloomberg Business Week* suggests VC firms—which remain flush with capital—are increasingly looking to B2B startups, including security software, automotive and healthcare technologies, where they see more growth potential and stability.

Valuations are at all-time highs, driven in part by the larger players' thirst for deals, meaning buyers must select their targets carefully. PE firms would do well to target providers with robust data collection and electronic health record (EHR) systems, enabling them to track patient outcomes and hospital readmission rates, and to compare their results against national and local averages. Buyers should also look at the quality of care delivered, the management team, the size and geography of the asset, and should seek out strong compliance programs, according to panelists on a *Home Health Care News* webinar.

Sources: Bloomberg, Forbes, Home Health Care News, MarketsandMarkets, Stoneridge Partners

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FEBRUARY

Feb. 5-8

30th Annual Rural Health Care Leadership Conference

Arizona Grand Resort & Spa
Phoenix

Feb. 8-10

Health Care Administrators Association (HCAA) 2017 Executive Forum

Bellagio Resort
Las Vegas

Feb. 9-10

2017 Wharton Health Care Business Conference

The Union League of Philadelphia
Philadelphia

Feb. 19-23

2017 Healthcare Information and Management Systems Society (HIMSS) Annual Conference & Exhibition

Orange County Convention Center
Orlando, Fla.

**Indicates that BDO is attending or sponsoring the event*

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