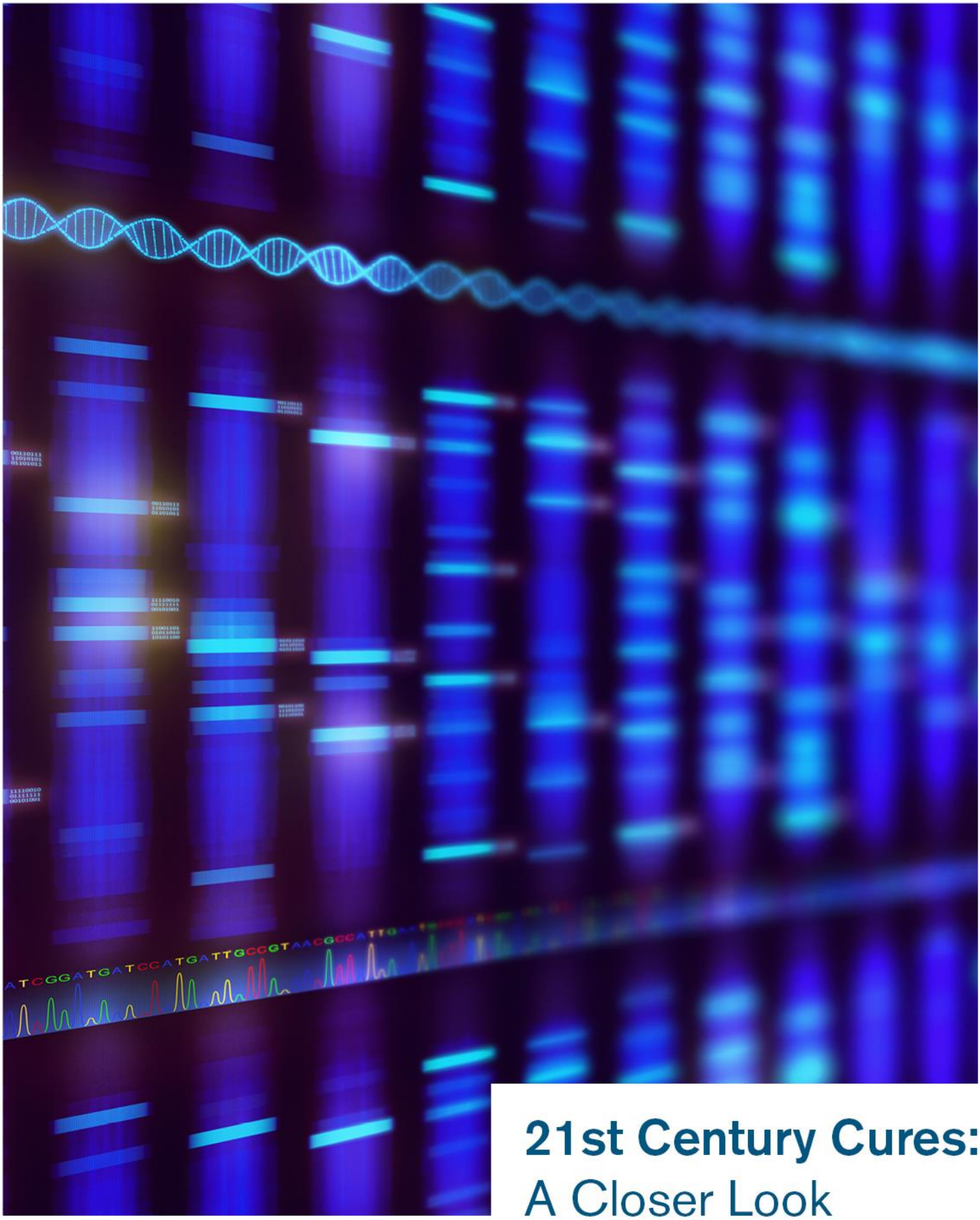
McDermott
Will & Emery

January 2017



21st Century Cures:
A Closer Look

McDermott Will & Emery

SPECIAL REPORT

Table of Contents

On December 7, 2016, the US Congress enacted the 21st Century Cures Act, substantial legislation intended to accelerate "discovery, development and delivery" of medical therapies by encouraging biomedical research investment, facilitating innovation review and approval processes, and continuing to invest in and modernize the delivery of health care. The massive bill also serves as a vehicle for a variety of other health-related measures. President Obama signed the Cures Act on December 13, 2016. This series of articles looks closely at several sections of the legislation, offering an examination of the provisions included therein and suggestions for implementation.

Tackling the Growing Problem of Mental Health and Substance Use Disorders

Jason B. Caron, Jennifer S. Geeter, Karen Owen Gibbs, Joel C. Rush and Marshall E. Jackson, Jr.

The 21st Century Cures Act includes portions of the Helping Families in Mental Health Crisis Reform Act of 2016, which was approved by the US House of Representatives in July 2016, but not advanced by the Senate.

A substantial portion of the 900+-page legislation relates to mental health and substance use disorders, in line with the rise in mental health and substance use disorder awareness over the last several years. The Act reflects a shift in thinking about the treatment of such disorders, which in the past was typically offered separate from other types of health care treatment, but now is more commonly integrated into physical care settings. The Cures Act calls for enhanced cooperation among agencies, provides funding for the development of innovative evidence-based models of treatment, provides for additional resources within the US Department of Health and Human Services (HHS), and includes a variety of provisions addressing mental health and substance use disorders within the context of law enforcement and judicial proceedings. The Act also enhances opportunities available under Medicaid waiver programs regarding mental health and substance use disorder treatment.

Most notably from a reimbursement perspective, the Cures Act reflects a concern that the expected parity in reimbursement for mental health treatment (per the Mental Health Parity and Addiction Equity Act of 2008) has not been achieved. The Act includes substantial requirements that HHS, the US Department of the Treasury and the US Department of Labor (DOL) develop compliance guidance (including detailed examples) related to the manner in which health plans address quantitative and non-quantitative limits related to behavioral health. The Act calls for increased "consumer friendliness" regarding parity expectations for mental health and substance use disorder treatment. Finally, the Cures Act allocates substantial funding ($1 billion over two years) to assist states in combatting the opioid and heroin abuse epidemic. The Cures Act does not make substantial changes in federal privacy laws or other controlling data use provisions, however, and therefore data sharing initiatives to coordinate the care of patients dealing with mental health or substance use disorders with other types of care may remain frustrated.

Increased Reimbursement and Funding for Mental Health and Substance Use Disorder Services

MEDICAID MENTAL HEALTH COVERAGE (SECTIONS 12001 TO 12006)

The Cures Act enhances Medicaid reimbursement for services related to mental health and substance use disorders. Chiefly, the Act clarifies that separate payment for the provision of mental health and primary care services provided to an individual on the same day is not prohibited under Medicaid, and, effective January 1, 2019, children receiving Medicaid-covered inpatient psychiatric hospital services are eligible for the full range of early and periodic screening, diagnostic and treatment services.

Additionally, the Act requires the Administrator of the Centers for Medicare and Medicaid Services (CMS) to take specific actions relating to mental health and substance use disorder treatment. First, the Administrator must conduct a study and submit a report to Congress within three years of the enactment of the Act on the provision of care to adults aged 21 to 65 enrolled in Medicaid managed care plans who are

receiving treatment for a mental health disorder in an Institution for Mental Diseases. Second, within one year of enactment of the Act, the CMS Administrator must issue a State Medicaid Director letter on opportunities to design innovative service delivery systems to improve care for individuals with serious mental illness or serious emotional disturbance. Third, the CMS Administrator must collect, analyze and—no later than two years after enactment of the Cures Act—report on data from states that participated in the Medicaid Emergency Psychiatric Demonstration Project established under Section 2707 of the Affordable Care Act.

MENTAL HEALTH PARITY (SECTIONS 13001 TO 13007)

The Cures Act takes steps to strengthen enforcement of mental health parity laws in a number of ways. First, it requires the HHS, DOL and Treasury to release compliance program guidance with illustrative examples of past findings of compliance and noncompliance with existing mental health parity requirements, including disclosure requirements and both quantitative and non-quantitative treatment limitations. Second, it requires HHS to issue guidance to assist health plans in complying with mental health parity requirements. Finally, the Act provides the Secretaries of HHS, Labor and Treasury with the authority to audit health plans to assess their compliance with mental health parity laws.

To ensure measurable success in enforcement of mental health parity laws, the Act requires HHS to produce an action plan for improved federal and state coordination related to the enforcement of mental health parity requirements. The action plan is expected to build on the recommendations of President Obama's Mental Health and Substance Use Disorder Parity Task Force Final Report released in October 2016. Specifically, the action plan must identify strategic objectives regarding how the various federal and state agencies charged with enforcement of mental health parity and substance use disorder equity requirements will collaborate to improve enforcement, and must provide a timeline for when such objectives shall be met and examples of how they will be met. Further, the Act requires the US Government Accountability Office (GAO), within three years of enactment of the Act, to conduct a study on the enforcement of existing mental health parity requirements, including compliance with non-quantitative treatment limitations; an assessment of how the Secretary has used its authority to conduct audits; a review of how the various federal and state agencies responsible for enforcing mental health parity requirements have improved enforcement; and recommendations for additional enforcement, education and coordination activities.

The Cures Act specifically aims to help men and women with eating disorders. This is the first time Congress has passed a bill that directly addresses eating disorders and their resultant harms. The Act dictates that group plans or individual health insurers that provide coverage for eating disorder benefits, including residential treatment, must provide such coverage consistent with mental health parity requirements. The Act also allows HHS, through the Director of the Office on Women's Health, to update resource lists and fact sheets related to eating disorders, and to increase public awareness of the following:

- Types of eating disorders;
- Seriousness of eating disorders (*i.e.*, prevalence, comorbidities and health consequences);
- Methods to identify, intervene, refer and treat eating disorders;
- Discrimination and bullying;
- Effects of media on eating disorders; and
- Signs and symptoms of eating disorders and treating individuals with eating disorders.

Further, the Act allows HHS to facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to identify individuals with eating disorders, provide early intervention services, refer patients to appropriate treatment, prevent the development of eating disorders and provide appropriate treatment to individuals with eating disorders.

STATE RESPONSE TO THE OPIOID ABUSE CRISIS (SECTION 1003)

A focal point in the diagnosis, treatment and prevention of substance use disorders has been the United States' opioid abuse crisis. The Cures Act provides $1 billion over two years for grants to states to supplement opioid use prevention and

treatment activities, such as improving prescription drug monitoring programs, implementing prevention activities, developing and providing training to health care providers, and expanding access to opioid treatment programs. The Act also attempts to provide accountability without increased burden on states by requiring grantees to report on activities funded by the grant in a substance use disorder block grant report.

MENTAL HEALTH AND SAFE COMMUNITIES (SECTIONS 14001 TO 14029)

The Cures Act provides several initiatives to increase community awareness, prevention and treatment of mental health and substance use disorders. Consistent with the thematic changes throughout the Act, the Cures Act shifts the focus from criminalization to crisis intervention and prevention. As part of that shift, the Act amends the Byrne Justice Assistance Grant Program to allow law enforcement to use funds for the creation of mental health response and corrections programs, including police crisis intervention teams. It also provides increased funding to train and educate state and federal law enforcement personnel and first responders on crisis de-escalation. Such initiatives include funding the federal Drug Court Grant Program to be used for the training of drug court professionals to identify and respond to these co-occurring disorders, and authorizing funding for the US Department of Justice (DOJ) VALOR Initiative to provide crisis response training and active-shooter training for federal, state and local law enforcement officials. To analyze the effectiveness of these training and education efforts, the GAO is required to submit a report to Congress detailing (1) the practices and procedures that federal first responders, tactical units and corrections officers are trained to use in responding to individuals with mental illness; (2) the application of evidence-based practices in criminal justice settings; and (3) recommendations on how the DOJ can improve information sharing and dissemination of best practices.

The Act provides for an increase in the data used in the criminal justice system to analyze the prevalence of offenders with mental health and substance use disorders. Specifically, the Act amends the America's Law Enforcement and Mental Health Project Act to allow state and local governments to use funds for the creation and deployment of behavioral health risk and needs assessments for mentally ill individuals in the criminal justice system. The Act also requires the Attorney General to collect and disseminate data regarding the involvement of mental illness in all homicides, as well as in deaths or serious bodily injuries involving law enforcement officers. Further, the Act requires the Comptroller General of the United States to submit a report to Congress detailing the federal, state and local costs of imprisonment for individuals with serious mental illness, including the number and types of crimes committed by mentally ill individuals.

> "The Act reflects a shift in thinking about the treatment of mental health disorders."

The Act establishes funding for various community-based initiatives aimed at preventing and treating mental health and substance use disorders. The Act reauthorizes and amends the Mentally Ill Offender Treatment and Crime Reduction Act (MIOTCRA) to allow state and local governments to use existing authorized grant funds for the operation of Forensic Assertive Community Treatment (FACT) Initiatives. FACT Initiatives provide high-intensity community-based services for individuals with mental illness who are involved in the criminal justice system. The amendment to the MIOTCRA also authorizes funds to award grants to nonprofit organizations for the creation of a National Criminal Justice and Mental Health Training and Technical Assistance Center, which would coordinate best practices for responding to mental illness in the criminal justice system and would provide technical assistance to governmental agencies that wish to implement these best practices.

The Act also amends the Residential Substance Abuse Treatment grant program to allot funds for the purpose of developing and implementing specialized residential substance abuse treatment programs that provide treatment to individuals with co-occurring mental health and substance use disorders.

Shifts in the National Approach to Mental Health and Substance Use Disorder Treatment

As noted previously, the Act demonstrates a change in language and attitudes regarding substance use disorders and behavioral health. In the legislation, Congress has shifted from using the term "substance abuse" to the term "mental health and substance use disorder." This is not merely a change in nomenclature, but places substantive emphasis on the medical (disorder) as opposed to the criminal (abuse). Also, as discussed in further detail below, the Act encourages the integration of mental health and substance use disorder treatment into primary care.

COMPREHENSIVE CARE MODEL (SECTION 9003)

To date, the health care system has been largely fractured between physical health and behavioral health. The Cures Act takes steps to bridge this gap. Specifically, the Act reauthorizes grants for comprehensive care models through the appropriation of $51.878 million for each of fiscal years 2018–2022. As part of this grant funding, the Act requires grant applicants to submit a plan to provide integrated services to patient populations with substance use disorders.

COMPASSIONATE COMMUNICATION ON HIPAA (SECTIONS 11001 TO 11004)

Per the Act, the sense of Congress is that the health care community is unsure of the permissible uses and disclosures of mental health and substance use disorder-related health information to family members and caregivers, and traces such confusion to the HIPAA regulations. The Act indicates that certain stakeholders feel that these HIPAA regulations have hindered the appropriate communication of health care information or treatment preferences. The sense of Congress is that clarification is necessary regarding existing permitted uses and disclosures of health information by health care professionals to caregivers of adults with serious mental illness, in order to facilitate care decisions in situations where serious mental health illness may affect the capacity of an individual to determine a course of treatment without assistance. The Cures Act requires the Director of the Office of Civil Rights to issue guidance that clarifies, among other things, the circumstances under which a health care provider may disclose protected health information of adults or minor patients to family members, caregivers, other individuals involved in the care of such patients, and law enforcement, particularly in situations where patients present a serious and imminent threat of harm to themselves or others.

HIPAA does not distinguish between different types of health information (except for psychotherapy notes as defined in 2 CFR 164.501), although state law and other federal laws often impose different regulatory obligations depending on the type of health information involved—for example, mental health and substance use disorder records. Although HIPAA imposes its own obligations that can be confusing or difficult to meet, in many cases the regulatory hurdle to sharing information about a patient's mental health and substance use disorder stems not from HIPAA but from state law and the federal law specifically addressing substance use disorder information. The Cures Act proposes no changes, however, to the relevant provision of the Public Health Services Act pursuant to which the Part 2 regulations are promulgated. Although the Substance Abuse and Mental Health Services Administration (SAMHSA), the agency that enforces Part 2, has recently sought to modify the regulations to facilitate data sharing by and among health care providers, care coordinators, health plans and other stakeholders, any proposed regulatory changes are limited to what the statute would permit.

Instead of attempting to modify the underlying statute, the Act proposes that the Secretary convene relevant stakeholders one year after promulgation of the final modifications to Part 2 to determine the effect of the regulations on patient care, health outcomes and patient privacy. To fully realize mental health and substance use disorder parity, patients suffering from these conditions must be able to access the same integrated patient outreach and care coordination efforts as patients with other medical disorders. The eventual Part 2 final rule may help advance this cause, but further legislative action may still be necessary. This working group may assist in maximizing what can be achieved by regulation and may help to guide further congressional action in balancing efforts to reckon with the particular privacy risks posed by the unauthorized sharing of information related to an individual's mental health and/or substance use disorder diagnosis or

treatment with enabling such information to be shared sufficiently to ensure that the health care system's approaching to caring for such patients is not hindered. In the interim, developers of digital health tools seeking to serve this patient population will need to develop and implement innovative consent models to comply with federal law.

CHANGES TO ENHANCE COORDINATION AMONG VARIOUS AGENCIES (SECTIONS 6002 AND 6031)

With the understanding that it will take input from many stakeholders to help solve the growing problem of mental health and substance use disorders, the Cures Act provides for increased collaboration between state and federal agencies and local communities. As part of the collaborative effort, the Act creates a coordinating committee charged with evaluating federal programs related to serious mental illness and providing recommendations to better coordinate mental health services for people with serious mental illness. The committee is made up of HHS, CMS, DOJ, DOL, the US Department of Veterans Affairs (VA), the US Department of Defense (DOD), the US Department of Housing and Urban Development (HUD), the US Department of Education and the Social Security Administration, as well as patients, health care providers, researchers, a judge and a law enforcement officer. The committee will make recommendations to Congress for better coordination of mental health services for people with serious mental illness and serious emotional disorders. The committee sunsets six years after the enactment of the Act. Further, the Assistant Secretary of SAMHSA is required to collaborate with other federal departments, including the DOD, VA, HUD and DOL, to improve care for veterans and support programs addressing homelessness.

STRENGTHENING LEADERSHIP AND ACCOUNTABILITY (SECTIONS 6001 TO 6009, AND 6021 TO 6023)

The Cures Act provides for several changes to the leadership and functions of SAMHSA to ensure that programs related to the prevention and treatment of mental illness and substance use disorders, and the promotion of mental health and recovery, are carried out in a manner that reflects the best available evidence-based practices. Specifically, the Cures Act establishes an Assistant Secretary for Mental Health and Substance Use to head SAMHSA and a Chief Medical Officer (CMO) within SAMHSA to (1) assist the Assistant Secretary in evaluating, organizing, integrating and coordinating programs within SAMHSA; (2) promote evidence-based best practices regarding the prevention and treatment of mental health and substance use disorders; and (3) assess the use of performance metrics to evaluate programs and activities, and ensure that such metrics are used to evaluate grant programs.

The Cures Act also codifies the existing Center for Behavioral Health Statistics and Quality to improve the quality of services provided by SAMHSA. The Act amends current law regarding the advisory councils for SAMHSA, Center for Substance Abuse Treatment (CSAT), Center for Substance Abuse Prevention (CSAP) and Center for Mental Health Services (CMHS) to (1) include the CMO and the Directors of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute of Alcohol Abuse and Alcoholism as members of the applicable advisory councils; (2) ensure that at least half of the appointed advisory council members for CMHS have a medical degree, doctoral degree in psychology, or an advanced degree in nursing or social work, and specialize in mental health; and (3) ensure that at least half of the appointment advisory council members for CSAP and CSAT have a medical degree, doctoral degree or an advanced degree in nursing, public health, behavioral or social sciences, or social work, or are a certified physician assistant, and have relevant experience.

The Act also creates the Interdepartmental Serious Mental Illness Coordinating Committee to evaluate federal programs related to serious mental illness and provide recommendations to better coordinate mental health services for people with serious mental illness. The committee is made up of the Secretary of HHS, the Assistant Secretary for Mental Health and Substance Use, the Attorney General, the Secretary of Veterans Affairs, the Secretary of Defense, the Secretary of Housing and Urban Development, the Secretary of Education, the Secretary of Labor, the CMS Administrator and the Commissioner of Social Security, as well as patients, health care providers, researchers, a judge and a law enforcement officer. As part of its oversight activities, the Committee must, no later than one year after the date of enactment of the Act and five years thereafter, submit to Congress a report evaluating, summarizing and making recommendations regarding advances in serious mental illness

and serious emotional disturbance research. The Committee will sunset six years after enactment of the Cures Act.

SAMHSA is required to develop a strategic plan no later than September 30, 2018, and every four years thereafter, for the planning and operation of activities carried out by SAMHSA, including evidence-based programs to increase access to quality services for individuals with mental and substance use disorders, and is required to collaborate with state and local government. The demand for mental health services is growing nationally, and with it there is an increasing shortage of mental health providers. To address this shortage, SAMHSA's strategic plan must including a strategy for encouraging individuals to pursue careers as mental health professionals and for improving the recruitment, training and retention of the mental health workforce. SAMHSA must make biennial reports available to Congress containing a review of SAMHSA's progress toward strategic priorities, goals and objectives identified in the strategic plan, as well as an assessment of programs and a description of coordination activities. The Cures Act also requires the Assistant Secretary to consult with stakeholders to improve community-based and other mental health services and improve the recruitment and retention of mental health and substance use disorder professionals.

The Cures Act provides for an increase in the oversight and accountability of mental health and substance use disorder programs. The Act establishes peer review groups made up of licensed and experienced professionals in the prevention, diagnosis, treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders, that are charged with reviewing grants, cooperative agreements or contracts related to mental illness treatment. The Act also outlines the roles and responsibilities of the Assistant Secretary for Planning and Evaluation at HHS, which include developing a strategy for conducting ongoing evaluations of key programs across the agency within 180 days of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016. Additionally, the GAO must conduct a study on programs funded under the Protection and Advocacy for Individuals with Mental Illness Act to review, among other things, (1) the programs carried out by states and private nonprofit organizations, (2) compliance with statutory and regulatory responsibilities, (3) responsibilities related to prospective clients or their family members, (4) availability of adequate medical and behavioral health treatment, and (5) denial of rights for individuals with mental illness.

NUMEROUS PILOT PROJECTS AND STUDIES ESTABLISHED OR REAUTHORIZED TO SUPPORT INITIATIVES RELATED TO MENTAL HEALTH AND SUBSTANCE USE DISORDERS (SECTIONS 7001 TO 7005, 8001 TO 8004, AND 9001 TO 9003)

Many of the efforts in the Cures Act to address mental health and substance use disorders are facilitated through various pilot programs and focus on mental health and substance use disorder awareness, prevention, treatment and intervention. As it pertains to the various pilot programs and studies, the Cures Act:

- Establishes the National Mental Health and Substance Use Policy Laboratory within SAMHSA and appropriates $14 million in grant funding for the period of fiscal years 2018–2020 to promote evidence-based practices and service delivery models through evaluation of models that would benefit from further development, and through expanding, replicating or scaling evidence-based programs across a wider area
- Reauthorizes the Priority Mental Health Needs of Regional and National Significance Program through the appropriation of $394.550 million for fiscal years 2018–2022 to support prevention, treatment and rehabilitation of mental health services and other programs to target responses based on mental health needs
- Reauthorizes the Priority Substance Use Disorder Treatment Needs of Regional and National Significance Program through the appropriation of $333.806 million for fiscal years 2018–2022 to improve the quality and availability of treatment and rehabilitation services for substance use disorder services in targeted areas
- Reauthorizes the Community Mental Health Services Block Grant through the appropriation of $532.571 million for fiscal years 2018–2022 to provide community mental health services for adults with serious mental illness and children with serious emotional disorders
- Reauthorizes the Substance Abuse Prevention and Treatment Block Grant through the appropriation of $1.858079 billion for fiscal years 2018–2022 to ensure ongoing training for substance use disorder prevention and

treatment professionals on recent trends in drug abuse in the state, evidence-based practices for substance use disorder services, performance-based accountability, and data collection and reporting requirements

- Reauthorizes and makes technical updates to grants for treatment and recovery for homeless individuals to support mental health and substance use disorder services through the appropriation of $41.304 million for each of fiscal years 2018–2022
- Reauthorizes and makes technical updates to develop and implement jail diversion grant programs to divert individuals with mental illness from the criminal justice system to community-based services through the appropriation of $4.269 million for each of fiscal years 2018–2022
- Reauthorizes and makes updates to grants for states to provide services to homeless individuals who are suffering from serious mental illness, or co-occurring serious mental illness and substance use disorders, through the appropriation of $64.635 million for each of fiscal years 2018–2022
- Requires the Secretary of HHS to conduct a study and submit a report to Congress within two years of enactment of the Cures Act on whether funding for the mental health and substance abuse block grants is being distributed to states and territories according to need, and to recommend changes if necessary
- Requires the Secretary of HHS to continue the National Suicide Prevention Lifeline program, including (1) coordinating a network of crisis centers to provide suicide prevention and crisis intervention services; (2) maintaining a suicide prevention hotline to link callers to local emergency, mental health and social services resources; and (3) consulting with the Secretary of Veterans Affairs to ensure that veterans calling the suicide prevention hotline have access to a specialized veterans' suicide prevention hotline
- Authorizes the Secretary of HHS to award grants to state and local governments, Indian tribes and tribal organizations to strengthen community-based crisis response systems or to develop, maintain or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities, and appropriates $12.5 million for each of fiscal years 2018–2022
- Reauthorizes the Garrett Lee Smith Memorial Act, which (1) codifies the suicide prevention technical assistance center to provide information and training for suicide prevention, surveillance and intervention strategies for all ages, particularly among groups at high risk; (2) appropriates $5.988 million for each of fiscal years 2018–2022; and (3) reauthorizes the Youth Suicide Early Intervention and Prevention Strategies grants to states and tribes through the appropriation of $30 million for each of fiscal years 2018–2022
- Establishes an Adult Suicide Prevention grant for individuals aged 25 years or older to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide, by appropriating $30 million for the period of fiscal years 2018–2022
- Reauthorizes $14.963 million in grant funding for each of fiscal years 2018–2022 to states, political subdivisions of states, Indian tribes, tribal organizations and nonprofit private entities to train teachers, appropriate school personnel, emergency services personnel and others, as appropriate, to recognize the signs and symptoms of mental illness, to become familiar with resources in the community for individuals with mental illnesses, and for the purpose of the safe de-escalation of crisis situations involving individuals with mental illness
- Requires the Secretary to disseminate information and provide technical assistance on evidence-based practices for mental health and substance use disorders in older adults
- Encourages the Director of the Centers for Disease Control and Prevention to improve, particularly through the inclusion of other states, the existing National Violent Death Reporting System
- Increases and extends authorization for the Assisted Outpatient Treatment grant program and

appropriates funding of $15 million in fiscal year 2017, $20 million for fiscal year 2018, $19 million for each of fiscal years 2019 and 2020, and $18 million for each of fiscal years 2021 and 2022

- Establishes the grant funding of $5 million for the period of fiscal years 2018–2022 to establish, maintain or expand assertive community treatment programs for adults with serious mental illness

Specific to efforts to increase and strengthen the health care workforce dedicated to mental health and substance abuse disorders, the Act:

- Reauthorizes Mental and Behavioral Health Education and Training grants to institutions of higher education or accredited professional training programs to support the recruitment and education of mental health care providers; creates a priority for programs that train psychology, psychiatry and social work professionals to work in integrated care settings, and for programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships; appropriates funding as may be necessary for fiscal years 2017–2021; and appropriates $50 million for each of fiscal years 2018–2022
- Authorizes the Secretary to establish a training demonstration program within the Health Resources and Services Administration (HRSA) to award five-year minimum grants for (1) medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings; (2) nurse practitioners, physician assistants, health service psychologists and social workers to provide mental and substance use disorder services in underserved community-based settings; and (3) establishment, maintenance or improvement of academic programs that provide training to improve the ability to recognize, diagnose and treat mental and substance use disorders
- Codifies the Minority Fellowship Program for the Secretary to increase the number of professionals who provide mental or substance use disorder services to underserved, minority populations, and to improve the quality of mental and substance use disorder prevention and treatment for ethnic minorities, and authorizes appropriations of $12.669 million for each of fiscal years 2018–2022
- Requires SAMHSA and HRSA to issue a report on national and state-level projections for the supply and demand of mental health and substance use disorder health workers and trends within the mental health and substance use disorder provider workforce
- Requires the Comptroller General to study peer-support specialist programs in states receiving grants from SAMHSA and report to Congress on (1) hours of formal work or volunteer experience related to mental health and substance use disorders conducted, (2) types of peer support specialist exams and codes of ethics required for such programs, and (3) recommended skill sets and requirements for continuing education

Strengthening Mental Health and Substance Use Disorder Care for Specific Vulnerable Populations (Sections 10001 to 10006, and 14001 to 14029)

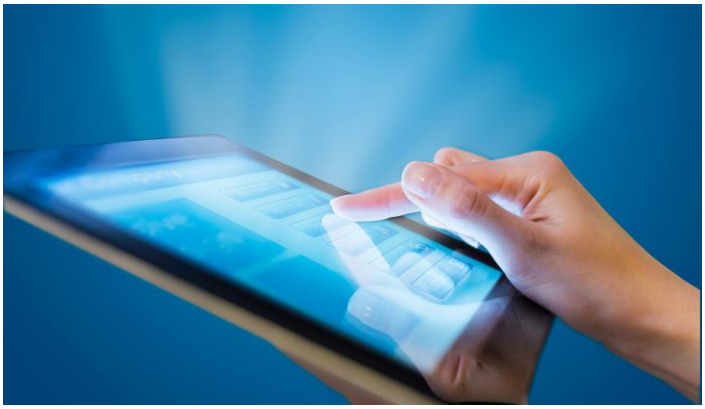
The Cures Act increases funding and initiatives aimed at certain vulnerable populations, including children, adolescents, women and non-violent offenders who suffer from mental health or substance use disorder issues. The Act reauthorizes and updates programs to provide comprehensive community mental health services to children with serious emotional disorders and provides for $119.026 million in funding for fiscal years 2018–2022. The Act also authorizes HRSA to award grants to promote behavioral health integration in pediatric primary care, including establishing eligibility requirements for statewide or regional pediatric mental health care telehealth programs in order to receive grant funding. As applicable to telehealth programs, the Act requires the state receiving the grant to match at least 20 percent of the federal funds. Further, the Act establishes a grant program to develop, maintain or enhance mental health prevention, intervention and treatment programs for infants and children at significant risk of developing or showing early signs of mental disorders, including serious emotional disorders, or social or emotional disability. Grant funding of $20 million for the period of fiscal years 2018–2022 is available for mental health

prevention, intervention and treatment programs for infants and children; however, states that receive the grant funding must match at least 10 percent of the federal funds.

The Act reauthorizes and makes technical updates to grants for substance use disorder treatment and early intervention for children and adolescents to provide early identification and services, and appropriates $29.6 million for each of fiscal years 2018–2022. The Act also reauthorizes the National Child Traumatic Stress Initiative (NCTSI), which supports a national network of child trauma centers, including university, hospital and community-based centers and affiliate members. As part of the NCTSI, the Act encourages collaboration between NCTSI and HHS to disseminate evidence-based and trauma-informed interventions, treatments and other resources to appropriate stakeholders, and provides for $46.9 million for each of fiscal years 2018–2022 to support such collaboration.

The Act also provides for grant funding aimed at women who suffer from mental health disorders. Specifically, the Act establishes a grant program for states to establish, improve or maintain programs for screening assessment and treatment services for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.

Consistent with the shift from criminalization to crisis prevention and intervention, the Act provides funding and initiatives to the criminal justice system to mitigate the criminalization of non-violent offenders with mental health and substance use disorders. The Act allows federal mental health court grant funds to be used for the creation of court-ordered outpatient treatment programs to prevent the escalation of mental health crises. Additionally, the Act requires the Attorney General and the Director of the Administrative Office of US Courts to create a Drug and Mental Health Court pilot program in at least one federal judicial district. As part of this program, low-level offenders who are mentally ill or addicted to narcotics would be eligible for diversion from prison if they comply with an intensive court-mandated treatment program. Many state and local governments operate similar problem-solving court programs, which have had success diverting eligible offenders, but under the current law, funding for such programs is allowable only for addressing substance abuse issues. Therefore, the Act updates the Treatment Alternative to Incarceration Program to allow state and local governments to use grant funds for these diversion programs for offenders with mental illness and co-occurring disorders. As part of the full spectrum of mental health and substance abuse disorder intervention, the Act amends the Second Chance Act to allow state and local governments to use re-entry demonstration project grant funds for the provision of mental health services, and to coordinate transitional services (including housing) for individuals re-entering society with mental illness, substance abuse problems or chronic homelessness. The initiatives aimed at non-violent offenders would likely reduce the risk of recidivism when a mentally ill offender is released.



Health Information Technology and Digital Health Tool Provisions

Jennifer S. Geetter, Daniel F. Gottlieb, Lisa Schmitz Mazur, Karen S. Sealander and Scott A. Weinstein

The 21st Century Cures Act includes provisions relating to health information technology (HIT) and related digital health initiatives, specifically in title IV.

Overview of the Health Information Technology Provisions in the Cures Legislation

The HIT provisions of the Cures legislation in general seek to

- Reduce administrative and regulatory burdens associated with providers' use of electronic health records (EHRs)

- Advance interoperability
- Promote standards for HIT
- Curb information blocking
- Improve patient care and access to health information in EHRs

Why These Provisions Matter

As public and private payers increasingly move from fee-for-service payments to value-based payment models, with a focus on maximizing health outcomes, population health improvement, and patient engagement, HIT—including EHRs and digital health tools—will be increasingly relied upon to collect clinical data, measure quality and cost effectiveness; assure continuity of care between patients and providers in different locations; and develop evidence-based clinical care guidelines. Further, newly implemented government programs like the Quality Payment Program will increasingly require clinicians and hospitals to use certified EHR technology (CEHRT) that meets certification guidelines specified by the Office of the National Coordinator for Health Information Technology (ONC) of the US Department of Health and Human Services (HHS). The continued evolution of these certification guidelines will also influence the development of digital health tools that are designed to interface or otherwise interact with CEHRT and assist providers to succeed under value-based payment models.

Congressman Tom Price (R-GA), a physician and a strong advocate for reducing burdens associated with the use of EHRs by providers, has been nominated to serve as HHS secretary in the administration of President-elect Donald Trump. Should Congressman Price be confirmed by the Senate, industry can likely expect HHS to use the new authority provided to it under the Cures legislation to reduce requirements of the Meaningful Use and Advancing Care Information programs, electronic clinical quality measure reporting requirements and other federal requirements relating to HIT that are perceived to make providers less efficient without improving quality or reducing costs. The new HHS secretary, however, will face competing pressures to leverage the expansion of HIT adoption and quality measure reporting to incentivize high-quality care at lower Medicare program costs.

What Is Required by These Cures Legislation Provisions

Reduction of Burdens – In response to clinician and hospital concerns about the regulatory and administrative burdens associated with EHR technology

- The HHS secretary is required within one year of enactment to develop with public comment from providers, suppliers, payers, technology developers and others a strategy and recommendations to reduce regulatory or administrative burdens related to the use of EHRs; this strategy must prioritize the Medicare and Medicaid EHR Incentive Programs, HIT certification, the Merit-based Incentive Payment System, the Hospital Value-Based Purchasing Program, Alternative Payment Models, and other value-based payment programs that the HHS secretary determines are appropriate;
- Physicians may delegate EHR documentation requirements to unlicensed assistants, or “scribes” (to the extent permitted by state law), provided the physician signs and verifies the documentation;
- The HHS secretary must encourage, keep or recognize voluntary certification of HIT for use in sites of services and medical specialties for which no certified technology is currently available, with the goal of making EHR certification more relevant and useful for those who use such EHRs.
- The HHS secretary must report to the new HIT Advisory Committee statistics on attestation of Meaningful Use under the Medicare and Medicaid EHR Incentive Programs to assist in informing standards adoption and related practices. The statistics must include, to the extent practicable, the number of providers who did not meet the minimum criteria necessary to attest, and must be made publically available on the HHS website;
- Authorizes $15 million to award grants, contracts or agreements to independent entities on a competitive basis to develop a required CEHRT reporting system to

address provider concerns that CEHRT technology does not always work as intended. As a condition of certification and attestation, CEHRT would be required to report measures developed by the independent entity on attributes that include

- Security
- User-centered design
- Interoperability
- Testing in real-world conditions

This provision aims to create an unbiased reporting system on EHR product usability, interoperability and security to assist providers in choosing product. This reporting system replaces a proposed "Star Rating" plan for EHR technology found in an earlier version of the legislation.

Advancement of Interoperability – In response to lawmakers' and stakeholders' concerns that while the Health Information Technology for Economic and Clinical Health Act (HITECH) increased the adoption by clinicians and hospitals of electronic health records, it did not sufficiently move the national needle on interoperability, the Cures legislation seeks to advance interoperability through

- Creating a definition for "interoperability" as HIT that
  - Enables the secure exchange of electronic health information with, and use of electronic health information from, other HIT without special effort on the part of the user
  - Allows for complete access, exchange and use of all electronically accessible health information for authorized use under applicable state or federal law
  - Does not constitute information blocking as defined in the Cures legislation
- Replacing the HIT Policy and Standards Committees with a new HIT Advisory Committee. This new committee will consist of at least 25 members, eight of whom shall be appointed by Congress, three appointed by the HHS secretary and the remainder appointed by the comptroller general of the US Government Accountability Office (GAO). Specific health sectors must be represented on the committee. This new federal advisory committee will address, in general, issues related to interoperability and privacy and security of health information and will also engage stakeholders to identify priorities for standards adoption. The Cures legislation provides additional direction on priority target areas on which the committee shall make recommendations. These directives are highly similar to those provided to the predecessor HIT Policy and Standards Committee in HITECH. This reiteration of areas for consideration likely signals that lawmakers believe that many of the objectives set forth in HITECH have not yet been fully achieved.

  One new priority area is patient matching, which relates to the unfulfilled directive to further interoperability between EHR systems. Specifically, the Cures legislation requires the new HIT Advisory Committee to make recommendations for "technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records." This directive and the call for a GAO study on patient matching indicates that policy makers recognize the importance of accurately identifying patients for electronic exchange of health information among providers in different organization and locations as well as for patient safety.
- Tasking ONC to create a process by which the public could submit complaints that HIT products or developers are not interoperable or engage in information blocking.
- Directing ONC to, within six months of enactment, convene stakeholders to develop or support (within 12 months of convening) a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. ONC and the National Institute of Standards and Technology are to provide technical assistance on developing this trusted exchange framework and common agreement. A process will be established through rulemaking by which health information networks may voluntarily adopt the framework and common agreement. Federal

agencies may by contracting or entering into agreements with health information exchange networks that require such networks to adopt the trusted exchange framework and common agreement.

Promotion of Standards – Lawmakers have increasingly recognized that stronger leadership is needed to ensure the consistent implementation and use of common standards. Accordingly, the Cures legislation requires the ONC to, not later than six months after the date on which the HIT Advisory Committee first meets, convene the HIT Advisory Committee to

- Enhance the use of common standards with deference given to standards published by private standards development organizations and voluntary consensus-based standards bodies.
- Identify priority use cases for HIT, focusing on use cases relating to
    - The implementation of Medicare's EHR Incentive Program, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program and any other value-based payment program determined appropriate by the HHS secretary
    - Quality of patient care
    - Public health
    - Clinical research
    - Privacy and security of electronic health information
    - Innovation in the field of HIT
    - Patient safety
    - Usability of health information technology
    - Individuals' access to electronic health information
- Identify existing standards and implementation specifications that support such use cases.
- Publish a report summarizing the findings of the analysis and make appropriate recommendations.
- Evaluate the need for a core set of common data elements and associate value sets to enhance the ability of CEHRT to capture, use and exchange structured electronic health information.

Starting five years after the enactment of the Cures legislation, and every three years thereafter, the ONC must convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations for maintaining or phasing out such standards and implementation specifications.

Combatting Information Blocking – The Cures legislation builds on the April 2015 *ONC Report to Congress on Health Information Blocking* and the voluntary ONC interoperability pledges signed earlier this year by companies that provide at least 90 percent of EHRs used by hospitals, and takes even stronger steps to combat information blocking by

- Defining "information blocking" as a practice, except as required by law or allowed by the HHS secretary pursuant to rulemaking, that
    - Is likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information
    - If conducted by an HIT developer, exchange or network, such entity knows or should know that such practice is likely to interfere with, prevent or materially discourage the access, exchange or use of electronic health information
    - If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information
- Establishing that information blocking practices may include
    - Practices that restrict authorized access, exchange or use of such information for treatment and other permitted purposes under such applicable law, including transitions between certified HIT systems
    - Implementing HIT in nonstandard ways that are

likely to substantially increase the complexity or burden of accessing, exchanging or using electronic health information

- Implementing HIT in ways that are likely to
  - Restrict access, exchange or use of electronic health information with respect to exporting complete information sets or in transitioning between HIT systems
  - Lead to fraud, waste or abuse, or impede innovations and advancements in health information access, exchange and use, including care delivery enabled by HIT

- Establishing new civil monetary penalties of up to $1 million per information blocking violation, including false attestations, that would be applicable to HIT developers, health information exchanges and networks. In contrast, provider penalties will be determined through notice and comment rulemaking. Importantly, for enforcement purposes, information blocking does not include any practice or conduct occurring prior to the date that is 30 days after enactment

IMPROVING PATIENT CARE AND IMPROVING PATIENT ACCESS TO THEIR HEALTH INFORMATION IN EHRS

- Requires the GAO to conduct two studies
  - A study on patient matching within two years of enactment. In calling for this study, lawmakers recognize that, with the increasing use of EHRs and the push toward interoperability, identifying accurately a single individual represented in multiple databases of different provider, payer and clearinghouse organizations is increasingly important for facilitating health information exchange and ensuring patient safety
  - A study on patient access to their own health information, including barriers to patient access
- Enables developers of HIT to participate in discussions with patient safety organizations without fear of liability risk in order to help improve the safety of HIT products for patients. Within four years after the date of enactment, the HHS secretary must submit to Congress a report concerning the best practices and current trends voluntarily provided, without identifying individual providers or developers
- Requires CEHRT to be capable of transmitting data to, and receiving data from clinician-led clinical data registries

Action Steps for Providers and Developers of HIT and Digital Tools

PROVIDERS AND DEVELOPERS OF HIT AND DIGITAL TOOLS SHOULD

- Review the definition of information blocking and take measures necessary to avoid engaging in practices that may constitute information blocking as defined in the new statute.
- Review applicable state laws that permit physician delegation to scribes to determine if the new federal flexibility applies.
- Assess potential interest in seeking representation on the new HIT Advisory Committee, either directly or through an association or other group (note that it is unclear how quickly after enactment ONC will form the HIT Advisory Committee, as a timeline for the transition from the HIT Policy Committee and the HIT Standards Committee to the new HIT Advisory Committee is not specified).
- Assess their implementation of HIT standards to determine the extent to which different standards and inconsistent implementation of the same standards may be prevalent.
- Be aware that changes to existing government requirements relating to EHRs are likely forthcoming.

PROVIDERS SHOULD

- Assess their unique regulatory environment to provide input on the forthcoming HHS efforts to reduce regulatory burdens.
- Determine whether their sites of service or specialties would benefit from CEHRT certified to meet their sites' or specialties' unique needs.

DEVELOPERS OF HIT AND DIGITAL TOOLS SHOULD

- Consider participating in stakeholder outreach efforts to advise ONC on
    - The establishment of a trusted exchange framework and common agreement
    - Criteria and measures for the new CEHRT reporting system
    - The HIT Advisory Committee's review of the existing set of adopted standards and implementation specifications every three years
- Adapt HIT development and testing strategies based on the criteria and measures established by the independent entity selected by ONC.
- Consider opportunities to partner with clinician-led organizations or professional societies to develop clinician-led clinical data registries.
- Keep abreast of new HIT requirements to inform the development of digital tools.
- Evaluate how best to work with patient safety organizations to promote shared learning to improve HIT safety now that privilege and confidentiality protection has been extended to HIT developers.

Required Exploration of Telehealth Solutions

Lisa Schmitz Mazur, Dale C. Van Demark, Jennifer S. Geetter, Daniel F. Gottlieb and Karen S. Sealander

The massive 21st Century Cures Act (Cures Act specifically calls out telehealth—the use of electronic information and communication methods to provide patient care when the health care professional and patient are not located at the same facility—as a potential means of delivering safe, effective, quality health care services to Medicare beneficiaries, and directs two federal agencies to investigate and report to Congress on its current and potential uses.

Overview of Key Telehealth Provisions in Cures Act

The legislation, if enacted, would require the Centers for Medicare & Medicaid Services (CMS) and Medicare Payment Advisory Commission (MedPAC) to report to the committees of jurisdiction in the House and Senate on the current and potential uses of telehealth in the Medicare program, to assist Congress in its ongoing assessment of Medicare coverage of telehealth services with a focus on the "originating site" requirement. The originating site—the site at which the patient is located at the time of the telehealth encounter—must be a certain type of health care facility that is located in a rural area, which significantly reduces the number of Medicare patients receiving care via telehealth.

Notably, Cures Act provides that it is the "sense of Congress" that eligible originating sites should be expanded and any expansion of telehealth services under the Medicare program should:

- Recognize that telehealth is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;
- Meet or exceed the conditions of coverage and payment with respect to the Medicare program if the service was furnished in person, including standards of care; and
- Involve clinically appropriate means to furnish such services.

Congress' "sense" statement communicates its desire for the development of a telehealth coverage expansion plan that contemplates the delivery of clinically appropriate types of services to Medicare beneficiaries in light of the applicable "standards of care", which are generally the same whether the patient is seen in person or through telehealth technologies, and other conditions of coverage requirements.

Relevant Background and Impact of Cures Act on Medicare Telehealth Coverage

Currently, Medicare coverage of telehealth is limited to circumstances where the following four categories of requirements are satisfied:

Originating Site. An originating site is the location of an eligible Medicare beneficiary at the time the telehealth service occurs. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in:

- A rural Health Professional Shortage Area (HPSA) located either outside of a Metropolitan Statistical Area (MSA) or in a rural census tract; or
- A county outside of a MSA.

The types of authorized originating sites are the offices of physicians or practitioners, hospitals, critical access hospitals, rural health clinics, federally qualified health centers, certain types of renal dialysis centers, skilled nursing facilities, and community mental health centers.

"In 2015, Medicare paid a total of $17,601,996 for telehealth services—an infinitesimal portion of the Medicare program's $630+ billion budget."

It is unclear whether Congress' "sense" that the originating site requirement warrants expansion relates to its facility type or geographic components, or both.

Distant Site Practitioner. Practitioners at the "distant site" who may furnish and receive payment for covered telehealth services are physicians, nurse practitioners, physician assistants, nurse-midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists and clinical social workers, and registered dietitians or nutrition professionals. The practitioner at the distant site must be licensed to furnish the service under state law. Unlike the originating site, there are no geographic or facility-specific requirements applicable to the distant site.

Telehealth Technologies. Only interactive audio and video telecommunications systems that permit real-time communication between the patient at the originating site and the practitioner at the distant site may be used.

Types of Services. While the list of covered telehealth services is expanding (albeit slowly), only a small defined set of services, including consultations, pharmacological management, office visits, and individual and group diabetes self-management training services, are currently covered by Medicare.

These limitations on Medicare coverage have severely limited the ability of health care practitioners to provide and get paid for the delivery of telehealth services to Medicare beneficiaries. To illustrate, in 2015, Medicare paid a total of $17,601,996 for telehealth services—an infinitesimal portion of the Medicare program's $630+ billion budget.

Congress' primary concern with expanding Medicare coverage of telehealth relates to cost. The Congressional Budget Office (CBO) acknowledges the difficulties associated with determining whether Medicare coverage for telehealth services would increase or decrease federal spending, as the extent to which telehealth services would be a substitute for (or reduce the use of) other Medicare-covered services is unclear.

According to CBO, if all or most telehealth services prevented the use of, or served as a substitute for, more expensive services, coverage of telehealth could reduce federal

spending. On the other hand, if telehealth services are used *in addition to* currently covered services, then increased coverage of telehealth services would increase Medicare spending. Because many of the proposals considered by Congress to date focus on expanding Medicare beneficiaries' access to health care services, CBO tends to generally view telehealth as cost prohibitive.

Cures Act directs CMS and MedPAC to gather and analyze the "hard data" necessary for Congress to better understand telehealth's potential to improve patient care to Medicare beneficiaries and its financial impact, and to identify appropriate adjustments to the Medicare program (with a focus on expanding the "originating site" requirements) in light of these findings.

TELEHEALTH RESEARCH ISSUE ASSIGNMENTS UNDER CURES ACT	
CMS	**MedPAC**
▪ The populations of beneficiaries whose care may be improved most in terms of quality and efficiency;	▪ The services currently paid for under the Medicare fee-for-service program;
▪ Activities by the Center for Medicare and Medicaid Innovation that examine the use of telehealth services in models, projects, or initiatives;	▪ The services currently paid for under private health insurance plans; and
▪ The types of high-volume services that might be suitable for telehealth; and	▪ Ways in which payment for telehealth services might be incorporated into the Medicare fee-for-service program.
▪ Barriers that might prevent its expansion.	

The gathering and analysis of this information will assist Congress and CBO to address certain ongoing financial and quality of care concerns about the use of telehealth outside of the narrowly defined "originating site." Addressing these longstanding concerns may help to open doors for the delivery of telehealth services to Medicare patients who are located in non-rural areas or who have conditions that can be managed, treated and/or observed outside of the four walls of a medical facility, such as at home or work.

Considerations for Health Care Providers and Technology Companies

While it is unlikely that Cures Act will have an immediate and significant impact on Medicare's approach to telehealth coverage, Cures Act (and other pieces of federal legislation focused on expanding telehealth services to Medicare beneficiaries) signals Congress' continued consideration of telehealth's ability to lower the costs of health care delivery and improve patient health. In light of this increased legislative activity and the change in administration, health care providers and telehealth technology companies should:

- Continue exploring ways to tailor their care delivery and revenue models to provide telehealth services to this large (and growing) segment of the population.
- Consider developing or participating in studies designed to test the efficacy and efficiency of telemedicine programs.
- Consider engaging with CMS and MedPAC on the issues in order to provide the federal government agencies charged with this investigation the best available industry information.
- Focus operational goals to achieve cost and value goals that are of concern to the government.

Modernizing Public and Private Research

Jennifer S. Geetter, Chelsea M. Rutherford and Lauren E. Parisi

Through National Institutes of Health (NIH) funding mechanisms, the 21st Century Cares Act prioritizes certain areas of medical innovation—namely cancer care, regenerative therapies, neurotechnologies and precision medicine—and will likely steer both public and private funding priorities in those directions for years to come. The Cures legislation also includes a number of other provisions aimed at revamping NIH operations. Many of these provisions focus on reducing administrative burdens and enhancing collaboration both within the NIH and between the NIH and other agencies or divisions. Although some of these changes will have minimal impact on private industry, many of them indicate more streamlined processes that may benefit researchers and grantees, among others. On the other hand, an enhanced focus on preventing and eliminating duplicative research efforts may raise the bar for prospective NIH awardees.

In addition to NIH funding mechanisms, Cures contains a number of other important research-related provisions. These include lightening the administrative burden on researchers by streamlining and minimizing duplication between regulations, encouraging collaboration between stakeholders and expanding privacy protections for research subjects, among others.

Funding NIH Initiatives

INNOVATION FUND

Section 1001 of the new Cures legislation provides the NIH with a dedicated, multi-year funding stream to support certain targeted research efforts, including the president's Precision Medicine Initiative, the vice president's Cancer Moonshot initiative, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and regenerative medicines. This section creates and funds the NIH Innovation Account to support these specific projects.

- ***Precision Medicine Initiative.*** The president's Precision Medicine Initiative encompasses funding streams, cross-agency directives and research ventures, all aimed at collecting and using genomic, lifestyle and other clinical data to help advance biomedical discoveries. A signature endeavor of the initiative is the development of a research cohort study of at least one million Americans who would participate by sharing genomic and clinical data, biospecimens and biofluids and other information for use by both researchers and participants themselves. The legislation authorizes a total of $1.45 billion over the next 10 years for this initiative.
- ***Cancer Moonshot Initiative.*** Currently led by Vice President Biden, the Cancer Moonshot initiative within the NIH's National Cancer Institute supports cancer research and focuses on accelerating cancer prevention, screening, treatment, and care. On December 5, 2016, the Senate amended Section 1001 of the Cures legislation in honor of Vice President Biden's late son, renaming it the "Beau Biden Cancer Moonshot and NIH Innovation Projects." This initiative is authorized to receive a total of $1.8 billion over the next 7 years.
- ***BRAIN Initiative.*** The BRAIN Initiative focuses on accelerating the diagnosis and treatment of brain disorders, such as Alzheimer's disease, by funding research into neurotechnologies. The legislation authorizes a total of $1.51 billion over the next 10 years for the BRAIN Initiative.
- ***Regenerative Medicines.*** The legislation also provides a total of $30 million in funding over the next 3 years for NIH, in coordination with the FDA, to award grants and contracts for clinical research using adult stem cells. Interestingly, the legislation requires grant recipients to bring matching private dollars to the project. As this matching private dollar requirement is not a current feature of NIH-funded stem cell research, it could act as a barrier to funding for institutions or effectively limit the amount of funding they can receive from NIH.

Though the Innovation Account, which finances each of these initiatives, is fully funded by Cures, an appropriation will still be required each year in order to release funds. Nonetheless, the

significant amount of funding earmarked for these initiatives highlights their role as high-priority areas of bipartisan interest and, for research entities, likely areas of significant growth over the next decade. Nor are these funding priorities only important for NIH scientists, as they present significant extramural funding opportunities for researchers focused in these areas.

NIH REAUTHORIZATION

The new legislation also reauthorizes the NIH for Fiscal Years 2018-2020 (the first reauthorization since 2006) and authorizes funding for each of those years ($34.8 billion in FY 2018, $35.6 billion in FY 2019 and $36.5 billion in FY 2020). While these levels are more robust that NIH's current authorization, the year-to-year increases are less than those proposed in the original bill (which would have seen a $1.5 billion increase in authorization levels per year). With several large-scale NIH initiatives receiving dedicated funding through the NIH Innovation Account, increases to NIH's funding may directly impact the number of grants NIH is able to award. Conversely, the Innovation funding could become an excuse for Congress to curb spending in other parts of the agency.

Reducing Administrative and Regulatory Burdens on Researchers

In addition to certain structural and administrative changes within the agency, the Cures legislation provides for review of and changes to a number of NIH rules and requirements that have historically been associated with significant administrative burdens. For example, the director of NIH is directed to review and revise as necessary NIH's regulations and policies related to financial conflict of interest disclosures for all research-funding agencies (*e.g.*, to minimize duplicative requirements). The NIH director is also directed to ease the administrative burdens associated with the monitoring of grant subrecipients, as long as those subrecipients meet certain requirements with respect to auditability and risk of noncompliance. Additionally, Section 2034 of the act permits the NIH director to utilize alternative grant structures that "may include collaborative grant models allowing for multiple primary awardees" to reduce the need for monitoring grant subrecipients.

Cures has also introduced new initiatives to promote efficiency and streamline research funded by NIH. By December of 2018, the secretary of HHS is required to report on the steps taken and procedures in place to prevent and eliminate unnecessary and duplicative biomedical research. A similar provision focuses on medical rehabilitation research at the National Center for Medical Rehabilitation Research at the NIH, which requires the HHS secretary and other agency heads to review its programs and take steps to coordinate across agencies to prevent duplication. These changes appear to reflect a desire to streamline research and preserve research funds without hampering contributions to scientific knowledge. The same section, however, also appears to require the directors of NIH's national research institutes and centers to personally review applications for competitive R-series grants made to their respective centers and make the final approval decision. As part of their sign-off, the directors must consider other projects on similar topics that are already funded by other agencies. This added requirement has the potential to significantly slow the grant approval process and may frustrate the act's overall focus on simplification and streamlining.

COLLABORATIVE EFFORTS

As part of the overall effort to streamline and simplify, the Cures legislation places a premium on collaboration among NIH's own research institutes and centers, with other federal agencies and with the private sector. There are several checks in place in the act to ensure these efforts are sustained and substantial. Cures directs the director of NIH and other heads of national research institutes to encourage and foster collaborative efforts. It also requires the director of NIH and the heads of each national research institute or center within the NIH to include in their formal triennial reports the exact amount of funding made available for collaborative research. Other provisions that encourage or require collaborative efforts with the private sector include:

- In carrying out the Precision Medicine Initiative, the secretary may collaborate with private industry and develop public-private partnerships. Section 2011 of the Cures Act requires the secretary, in his or her report on the Initiative, to explain what steps have been taken with respect to consulting with experts.
- In promoting and providing opportunities for new

researchers and earlier research independence, the director of the NIH shall coordinate with, among others, "professional and academic associations and academic institutions" under Section 2021 of the act in order to better inform programs related to "the training, recruitment, and retention of biomedical researchers."

- Section 2031 of the act requires the NIH director to consult with "researchers, patient advocacy groups, and industry leaders" in developing the NIH Strategic Plan.
- The NIH will be represented on a Working Group, established by Section 2063 of the act, in which the research community, patients, experts in civil rights, health information technology developers, experts in data privacy and security, health care providers and bioethicists will also be represented, on the uses and disclosures of protected health information for research.

STREAMLINING FDA AND HUMAN SUBJECTS RESEARCH REQUIREMENTS

In recognition of the additional compliance burden placed on researchers subject to both FDA and Common Rule regulatory regimes governing human subjects research, Section 3023 of the Cures Act directs the HHS secretary to harmonize these regulations—found at 21 C.F.R. pt. 50 and 45 C.F.R. pt. 46, respectively—within three years from Cures' enactment. Specifically, the secretary will be modifying and updating both the FDA and Common Rule regulations to:

- Minimize instances of "regulatory duplication and unnecessary delays";
- Align with current practices in the context of multisite and cooperative research projects; and
- Facilitate the use of collaboration and shared review and oversight pathways among entities engaged in human subjects research.

In developing these changes, the legislation instructs the HHS secretary to consult with various stakeholders, including researchers, providers, drug and device developers, as well as engaging with local stakeholders to ensure the protection of vulnerable populations. This initiative is good news for researchers, on whom the regulatory burden will be minimized in the context of human subjects research. Nonetheless, this legislation does not address all the areas in need of harmonization, nor does it address divergences between FDA, Common Rule, and Health Insurance Portability and Accountability Act (HIPAA) regulations.

> "Cures requires NIH to foster and encourage collaboration among NIH-funded human subjects research projects that collect similar data."

STREAMLINING RESEARCH USE OF HEALTH DATA

Cures' broad emphasis on facilitating research is reflected in efforts to remove certain barriers to leveraging the existing HIPAA preparatory to research pathway set forth at 45 CFR § 164.512(i)(1)(ii). The preparatory to research pathway allows researchers to review protected health information (PHI) in connection with activities that proceed and help prepare for the conduct of an actual research study; for example, identifying potential subjects or refining a research protocol. The current pathway does not permit PHI to leave the premises of the applicable covered entity during such activities. In the current digital world, this premises requirement—a reflection of a world of medical record departments in hospital basements with paper records—is no longer well suited. Section 2063 of the Cures legislation modernizes this requirement by specifying that a researcher's remote access of PHI held within a covered entity's electronic record system does not constitute the removal of the PHI from the covered entity's premises, provided that HIPAA-compliant privacy and security safeguards are maintained by the covered entity and researcher, and where the researcher does not copy or otherwise retain the protected health information. While Cures directly addresses questions posed by covered entities about remote access, further legislative or regulatory activity may be necessary to clarify what constitutes the "premises" of the covered entity, as so many covered entities

do not maintain local storage (digital or otherwise) of the records but rather rely on business associates. In addition, Cures does not provide direction as to any required harmonization of HIPAA and the Common Rule with respect to how such preparatory to research activities should be structured given that the Common Rule's definition of outright research in 45 CFR § 46.102(d) includes "research development."

Another of the provisions in Cures requires NIH to foster and encourage collaboration among NIH-funded human subjects research projects that collect similar data. While the goals of this provision—to increase the subject population size and diversity—are valuable, it remains an open question whether such collaboration would be embraced, or even feasible, in our current national research environment, in which securing funding is a deeply competitive process and significant research findings are often fiercely protected prior to publication.

Changes to the Research Process

The Cures legislation also lays the groundwork for potentially significant changes to the research process for both federally and privately funded researchers. The general intent and reoccurring theme of Cures is stated best in Section 2034 of the act: to "harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants." Despite this intent, certain new provisions in Cures have the potential to create additional regulatory and compliance hurdles for researchers. For instance, research entities seeking funding may be required to conform with new or modified policies with respect to the reproducibility of NIH-funded scientific research, preclinical and clinical experiment design, the types of variables that should be measured and analyzed (*e.g.*, social and other determinants that contribute to health disparities), proper levels of rigor in statistical methodology and analysis and data sharing. The legislation requires the director of NIH to convene a working group to address these issues, and based on the group's recommendations, the director is required to develop or update policies as appropriate.

Separate from this working group, the legislation also permits the director of the NIH to require researchers to share scientific data, to the extent feasible, generated from any NIH-funded research. Cures does not set forth details about what this data sharing requirement would entail; however, in the future, this may pose additional compliance hurdles for NIH awardees.

Changes to Certificates of Confidentiality

Cures also expands data privacy protections for research subjects by revising NIH's certificate of confidentiality authority. Certificates of confidentiality generally protect against compulsory legal demands, such as court orders and subpoenas, for certain identifying information about a research participant. The NIH has a current process to grant certificates of confidentiality, but such authority is discretionary and limited to certain types of research (*e.g.*, studies tackling certain mission areas of the NIH). Section 2012 of Cures newly requires the NIH to issue such certificates for federally funded research that collects "identifiable, sensitive information," and permits the NIH to issue certificates for privately-funded research collecting the same. The new legislation expands the scope of the certificate and affirmatively prohibits certificate holders from disclosing or providing the name of research subjects—or any information, document or biospecimens containing identifiable, sensitive information collected during the research—to persons not connected with the research. There are limited exceptions to this disclosure prohibition (*e.g.*, subject consent and medical treatment); however, one exception that may exist to further Cures' data sharing goals permits disclosures made for the purposes of other scientific research that complies with applicable federal human subjects research regulations. It also explicitly protects such information created or compiled for research purposes against compulsory legal demands (unless a subject consents).

The act also introduces a new information standard: "identifiable, sensitive information." Cures defines this as information about an individual that is gathered or used during the course of research through which an individual is identified or for which there is "at least a very small risk" that the individual could be identified via a combination of the information, the

request and other available data sources. It is not directly clear how this new standard and new requirement reconcile with other research-related information specifications, such as the statistical de-identification standard under HIPAA, but the standards do appear substantially similar.

Key Areas of Focus

In addition to funding, however, the legislation directs the NIH (and, in certain instances, the FDA and other HHS agencies) to consider a host of other, broader focal points. In doing so, Cures creates opportunities for the NIH and others to think critically about specific areas of potential improvement in current research processes and priorities and to pursue such improvements. Important focal points include:

- Addressing pressing, current public health crises (*e.g.*, antimicrobial resistance, opioid epidemic);
- Supporting research innovations and the next generation of scientists; and
- Evaluating and modernizing current research infrastructure (*e.g.*, via exploring diversity among research participants, reevaluating laboratory animal regulations and policies, and creating a new global pediatric clinical study network and a new task force on research regarding pregnant and lactating women).

While the new administration may not choose to actively pursue improvements in these areas, the statute includes a number of tools that the NIH may utilize if it chooses to do so. First, as part of the new Research Policy Board created under Cures, the NIH has the opportunity to work with the heads of other departments and agencies to overhaul research regulations and prioritize research aims across funding agencies. The legislation also includes funding mechanisms that give NIH significant control in structuring the funding of new scientific innovations. These include the Eureka Prize competitions and the Next Generation of Researchers Initiative, the latter of which could result in significantly more grant award opportunities for early-stage researchers. Cures also permits national institutes and centers within NIH, with approval from the director, to use alternate transaction structures to fund "high-risk, high-reward research," and encourages the support of such "cutting-edge" research to address major current health challenges. Should it choose to do so, these tools likely give the NIH significant latitude to direct funding—and, moreover, policy—as it deems fit, based on its review and evaluation activities.

Expanding Hospital Site-Neutral Payment Exceptions and Other Payments Changes

Emily J. Cook, Monica Wallace and Eric Zimmerman

The 21st Century Cures Act includes a host of Medicare payment related changes, primarily in titles XV and XVI. The bill includes portions of the Helping Hospitals Improve Patient Care Act of 2016, which was previously approved by the US House of Representatives in June 2016 but not advanced by the Senate. The Helping Hospitals portions broaden exceptions under much-maligned legislation enacted in 2015 that will equalize Medicare payments furnished in new outpatient facilities not on a hospital's campus beginning in 2017. The legislation will provide much-needed relief for hospitals that were caught off guard by the 2015 legislation. Additionally, the bill makes almost a dozen other payment and regulatory changes of interest to hospitals and post-acute care providers.

Site-Neutral Payments for Off-Campus Provider-Based Hospital Services (Sections 16001 and 16002)

Section 603 of the Bipartisan Budget Act of 2015, enacted November 2, 2015, limits Medicare payments for items or services (other than services furnished by a dedicated emergency department) furnished at an off-campus outpatient department of a hospital, unless that location was billing as an outpatient department of a hospital prior to the date of enactment. Beginning January 1, 2017, Medicare will pay for such items and services under a modified fee schedule based on the Medicare Physician Fee Schedule, instead of under the Hospital Outpatient Prospective Payment System (OPPS). For more information on plans to implement the original legislative restrictions, see McDermott's *On the Subject* summarizing the Centers for Medicare and Medicaid Services' (CMS's) final regulations published November 14, 2016.

Almost immediately after the Bipartisan Budget Act was approved, hospitals besieged Congress with complaints about projects—some requiring substantial capital investment—that were already underway and that were undertaken with the expectation of higher Medicare payments under the OPPS. Many hospitals complained that implementation of Section 603, as enacted, would disrupt long-standing plans and result in discontinued services.

The Cures legislation extends grandfather protection to some of these projects. Under the original legislation, a project would not be subject to the site-neutral payment policy if the hospital was furnishing services to Medicare beneficiaries at an off-campus outpatient department location on or before November 2, 2015. Under the new bill, an off-campus outpatient department also could be eligible for higher OPPS payments in 2017 if the host hospital submitted a voluntary provider-based attestation to CMS pursuant to 42 CFR Section 413.65(b)(3) before December 2, 2015. Under separate guidance from CMS governing submission of provider-based attestations, for a hospital to have taken this step, the construction of the new off-campus outpatient department would have had to be complete and the hospital accepting or poised to accept patients.

While this new exception benefits only hospitals with complete projects that fell just short of the furnishing services deadline, another exception in the Cures legislation may apply to more facilities. For services furnished on or after January 1, 2018, the new legislation would except from the site-neutral policy off-campus outpatient department locations that had a "binding written agreement with an outside unrelated party for the actual construction" of the new off-campus outpatient department before November 2, 2015. To be eligible under this alternative exception, the host hospital must also (1) file a provider-based attestation for the new off-campus outpatient department within 60 days of the date of the enactment of the legislation, (2) submit a certification to CMS within 60 days of the date of the enactment that the hospital had the required binding written construction agreement, and (3) add the off-campus outpatient department to the host hospital's Medicare enrollment form.

While the narrower relief for off-campus outpatient departments with provider-based attestations filed before December 2, 2015, would be applicable only for 2017, the broader relief for off-campus outpatient departments with construction agreements in place as of November 2, 2015, (which would include hospitals eligible for the 2017 exception) would not be available until January 1, 2018. Hospitals able to take advantage of only the broader relief would not be eligible for OPPS payments during 2017 and instead would be subject to lower modified payments until January 1, 2018.

The new legislation also would provide an exemption for off-campus outpatient departments of certain cancer hospitals that file provider-based attestations within 60 days of the date of enactment of the legislation (for departments meeting provider-based requirements between November 2, 2015, and the date of enactment) or within 60 days of the date of meeting provider-based requirements.

Hospitals that were disadvantaged by the 2015 legislation and that can take advantage of one of the new exceptions should take immediate steps to file required paperwork before the specified deadlines.

Hospital Supervision Requirements (Section 16004)

The new bill bars CMS from enforcing direct physician supervision requirements for outpatient therapeutic services in Critical Access Hospitals (CAHs) and small rural hospitals (hospitals in rural areas with no more than 100 beds) through the remainder of 2016.

In 2009, CMS changed the supervision requirements for outpatient therapy services at all hospitals, requiring that a supervising physician be physically present in the department at all times when Medicare beneficiaries are receiving outpatient therapy. However, after considerable pushback, CMS imposed a temporary moratorium on enforcement at CAHs and small rural hospitals. CMS announced in November 2013 that it would end the moratorium effective January 1, 2014, and began implementing and enforcing the supervision requirement for 2014. In late 2014 and again in late 2015, Congress approved similar legislation providing protection for the balance of those years.

Given that 2016 is almost over, this bill provides little prospective relief. Nonetheless, the change will be helpful for hospitals that find themselves the subject of a supervision-related enforcement action in 2016, as this legislation should absolve such hospitals of any wrongdoing.

Hospital Inpatient Short-Stays (Section 15001)

In recent years, policymakers have wrestled with how to respond to an increased frequency of one-day inpatient admissions and extended observation stays in outpatient cases. The Cures bill takes an important step toward eliminating the financial incentives that drive these trends. Specifically, the legislation requires CMS to develop HCPCS codes (used to code outpatient services) associated with 10 surgical MS-DRGs that commonly have a one-day length of stay. While not stated expressly in the legislation, the purpose of establishing these HCPCS codes is to facilitate a crosswalk that will better connect inpatient and outpatient coding and payment systems for hospitals, with the goal of identifying surgeries appropriate for site-neutral payment between inpatient and outpatient settings.

Hospital Readmissions Reduction Program (Section 15002)

The Cures legislation makes changes affecting the Hospital Readmissions Reduction Program to account for the socioeconomic status of a hospital's patients. Under the current program, hospitals with risk-adjusted readmission rates greater than the national average have payments made under the Inpatient Prospective Payment System (IPPS) reduced. Some hospitals have complained that the current Program does not adequately account for the socioeconomic status of a hospital's patients, which, as these hospitals assert, can contribute to post-discharge non-compliance and subsequent readmissions.

Under the new bill, CMS will be required to make adjustments based on the patient's socioeconomic status. Initially, the adjustment will be based on the proportion of patients dually eligible for Medicare and Medicaid that the hospital serves. After completion of previously required studies, CMS may use different standards to account for socioeconomic status.

Documentation and Coding Payment Adjustments (Section 15005)

The Cures bill would further reduce payments under IPPS with more "documentation and coding" adjustments. When CMS implemented new MS-DRGs in 2008 to better classify inpatient discharges under the IPPS, the agency assumed that payments to hospitals would increase because of enhanced coding accuracy. Pursuant to administrative and legislative action, CMS made a series of adjustments to IPPS payments to recoup perceived increases in payments resulting from improved "documentation and coding." However, CMS committed to undo the adjustments in 2018 by making a one-time 3.2 percent payment increase. The Medicare Access and CHIP Reauthorization Act of 2016 clawed back some money by prolonging the restoration of that adjustment by requiring that it be made in 0.5 percent

increments over six years (rather than all at once), and by withholding the 0.2 percent remaining balance.

The Cures bill would further reduce that 0.5 percent adjustment for 2018 by 0.0412 percentage points, to 0.4588 percent; the annual adjustment would return to 0.5 percent for fiscal years 2019 to 2023. Congress took this step as a way to offset the spending increase that would result from other changes in the bill, including the additional relief provided under the site-neutral payment provisions.

Rural Community Hospital Demonstration Program (Section 15003)

The Rural Community Hospital Demonstration Program provides Medicare cost-based reimbursement to certain small rural hospitals that do not quality for cost-based reimbursement under the CAH designation. The new legislation would extend the Demonstration Program for an additional five years (through the end of calendar year 2021) and re-open the application process to hospitals in any state, albeit with priority to hospitals in low population density states.

Durable Medical Equipment Provisions (Sections 16005, 16007 and 5002)

The Patient Access and Medicare Protection Act of 2015 (PAMPA) delayed for one year (until January 1, 2017) the application of durable medical equipment (DME) competitive bidding program (CBP) ceiling payment rates for accessories furnished in connection with complex rehabilitative technology power group three wheelchairs. The Cures bill further delays the application for another six months, until July 1, 2017.

The Cures bill also would delay application of CBP ceiling payments to items in areas not yet subject to CBP. Under current law, CMS based payment on 50 percent of the CBP single payment amount (SPA) and 50 percent of the fee schedule amount for items furnished between January 1, 2016, and June 30, 2016; payments for items furnished effective July 1, 2016, were based 100 percent on the SPA. Under the Cures bill, CMS would extend the 50/50 blend through December 31, 2016, and then implement 100 percent of the SPA amount effective January 1, 2017, effectively delaying implementation of lower payments by six months.

The bill also would offset the cost of these and other changes by advancing already enacted legislation that caps Medicaid payments for select DME items at Medicare payment amounts from the current effective date of January 1, 2019, to January 1, 2018. Current law will begin to cap the amount the federal government will pay states for DME items furnished to Medicaid recipients when sold pursuant to a fee schedule at the rate that would have been paid under Medicare. This existing cap applies only to items sold pursuant to a Medicaid fee schedule, so the cap should not apply to items sold pursuant to negotiated agreements with Medicaid Managed Care plans or furnished pursuant to a pharmacy benefit.

Physical Therapy Services (Section 16006)

The Cures bill allows physical therapists furnishing outpatient physical therapy services in a health professional shortage area, a medically underserved area or a rural area to use specified *locum tenens* arrangements for payment purposes in the same manner as such arrangements are used to apply to physicians furnishing substitute physician services for other physicians.

Long-Term Care Hospitals (Sections 15004 and 15006-10)

The Cures bill provides relief for long-term care hospitals (LTCHs) under a one-year moratorium on the "25 percent rule," which would otherwise penalize LTCHs that admit more than 25 percent of their patients from a particular acute care hospital. As modified by Cures, implementation of the 25 percent rule will be suspended during federal fiscal year 2017 (October 1, 2016, through September 30, 2017). The legislation also establishes a number of other new policies and technical changes to existing LTCH statutes, but most of the changes will affect only limited subsets of LTCHs with special circumstances.

The legislation provides an exception to the current moratorium on new LTCH beds to allow for an expansion in the number of LTCH beds at satellite locations of existing LTCHs, so long as the satellite expansion project was in place as of April 1, 2014. Other changes for LTCHs in Cures include

modifying the calculation methodology for high-cost outlier payments to LTCHs; removing less favorable length-of-stay provisions for determining when to apply certain site-neutral payment policies that are applicable to hospitals that converted to LTCHs after December 1, 2013; reclassification of certain LTCHs focusing on cancer care to provide for cost-based reimbursement for such hospitals; and temporarily suspending site-neutral payment policies for LTCHs specializing in spinal cord injuries and certain discharges related to severe wound care.

Ambulatory Surgical Centers (Sections 16003 and 4002)

Under the Medicare Meaningful Use Program, physicians must conduct a threshold amount of patient encounters in settings with Certified Electronic Health Record (EHR) technology to meet Program requirements. Patient encounters in the Ambulatory Surgical Center (ASC) setting count, but because ASCs were not included in the original Meaningful Use Program, there is no option available in the ASC setting. The ASC community has argued that this dynamic discourages physicians from furnishing Medicare cases in ASCs. The Cures bill would prohibit CMS from penalizing under the current Meaningful Use Program or its equivalent under the new Merit-Based Incentive Payment System physicians who furnish "substantially all" of their Medicare-covered professional services in an ASC, until such time as CMS certifies an EHR system for ASCs.

Medicare Advantage and Small Business Insurance Market Reforms

Ankur J. Goel, Kate McDonald, Jeremy Earl and Mary S. Moll

In Depth

The 21st Century Cures Act includes provisions affecting Medicare Advantage, drawing from the bipartisan Senate Finance Committee's Chronic Care Working Group, and the small employer health insurance market. These provisions are primarily contained in titles XVII and XVIII of the new legislation.

The law includes the following changes, among several others affecting Medicare Advantage, Part D and insurance for small employers:

- Allowing Medicare beneficiaries with end-stage renal disease (ESRD) to enroll in Medicare Advantage plans beginning in 2021
- Requiring changes to the risk adjustment methodology, beginning in 2019
- Postponing the Centers for Medicare & Medicaid Services' (CMS's) ability to terminate contracts with Medicare Advantage Organizations that do not achieve Star Ratings of at least three Stars for successive years until plan year 2019

Expanding Medicare Advantage to Include End-Stage Renal Disease Beneficiaries (§ 17006)

Starting 2021, all Medicare beneficiaries suffering from ESRD will have the option to enroll in a Medicare Advantage plan. Coverage for kidney transplants will be carved out of the Medicare Advantage plan and reimbursed under Parts A and B. In light of this change, the secretary of the US Department of Health and Human Services (HHS) must consider (1) incorporating into the Star Rating system a quality measure specific to ESRD coverage and (2) revising the Medicare

Advantage risk adjustment model to include additional factors regarding chronic kidney disease.

Providing ESRD patients with expanded access to Medicare Advantage coverage could dramatically reshape treatment of and payment for the treatment of Medicare beneficiaries with chronic kidney disease. The Medicare Payment Advisory Commission endorsed opening Medicare Advantage to ESRD patients in 2000. More recently, the bipartisan Senate Finance Committee's Chronic Care Working Group promoted this policy in its draft legislation. Prominent patient and industry groups including the America's Health Insurance Plans and the National Kidney Foundation endorsed this effort to open access to Medicare Advantage to ESRD patients. Other stakeholders expressed concern that risk adjustment payments for ESRD patients may be inadequate to cover the cost of dialysis treatment.

These changes are a number of years away, but in preparation:

- Plans should consider how including the ESRD population in the risk pool will affect rate development and their existing provider agreements.
- Plans should evaluate other key factors that could be incorporated into the risk adjustment model to best represent the risk of covering ESRD beneficiaries.
- Plans should monitor CMS for requests for information, rulemaking and other guidance regarding updates to the Medicare Advantage risk adjustment model.
- Providers should evaluate their current membership in Medicare Advantage plan networks and the capacity and volume assumptions underlying their participation agreements.

Modifying the Medicare Advantage Risk Adjustment Model Beginning in 2019 (§ 17006)

The Act also directs numerous changes to the Medicare Advantage risk adjustment model beginning in 2019. Under the legislation, the model must take into account the total number of diseases or conditions of a Medicare Advantage enrollee. Additionally, CMS would be able to use two years of diagnosis data when determining beneficiary health conditions. The model must also separately adjust for "full-benefit" and other dual-eligibles. Finally, the secretary of HHS must evaluate the inclusion of additional factors, including mental health and substance abuse, into the model.

These changes to the risk adjustment model will impact all Medicare Advantage plans. The changes are intended to result in more favorable treatment for plans with patients who have chronic conditions. The modifications to the risk adjustment model were previously included in the Senate Finance Committee's Chronic Care Working Group draft legislation, and a number of patient and industry groups have endorsed the effort.

CMS has recently modified the risk adjustment model to account for the risk of enrolling different groups of beneficiaries (*e.g.,* "full-benefit" dual-eligible beneficiaries). In 2016, CMS announced that the 2017 risk adjustment model would be separated into six subgroups based on dual eligibility status.

In preparation for the changes:

- Plans should consider how a modified risk adjustment model will impact rate development and existing capitated provider agreements.
- Plans should evaluate other key factors that could be incorporated into the risk adjustment model to best represent the risk of covering beneficiaries with chronic conditions. Plans should monitor CMS for requests for information, rulemaking and other guidance regarding updates to the Medicare Advantage risk adjustment model. Traditionally, CMS issues changes and proposed changes through the Advance Notice and Final Rate Announcement process, which for plan year 2019, is expected to kick off in February 2018. However, CMS will likely begin the process of considering adjustments to the model before then.

Star Rating Exclusion Delay (§ 17001)

Another section of the Act suspends CMS's authority to terminate a Medicare Advantage plan solely on the basis of

the plan's performance in the Star Ratings system through the end of plan year 2018. CMS has in the past voluntarily chosen not to exercise its termination authority, but announced in the 2016 and 2017 Call Letters that it would begin doing so, and issued at least one non-renewal notice in 2016 that will be effective December 31, 2016.

The Star Ratings system is central to CMS's goal of improving the quality of services provided to Medicare beneficiaries. Star Ratings help beneficiaries compare plan quality and determine plan bonus payments. CMS currently has the authority to terminate Medicate Advantage plans for failure to achieve a rating of at least three Stars in at least one out of three consecutive years.

Because the Act also requires CMS to continue to study the impact of socioeconomic status on Star Ratings, this suspension appears to stem from concerns that the Star Ratings system

unfairly penalizes plans that enroll disproportionate numbers of low-income and disabled beneficiaries. In 2015, CMS engaged RAND Corporation to study this issue and concluded that there was some evidence of within-contract disparities between low-income/disabled members and other members at least for a subset of the Star Ratings measures. The size of the effect differed across measures and was not exclusively negative. In an effort to address these within-contract disparities, CMS implemented an adjustment factor for the 2017 Star Ratings based on each contract's low-income subsidy, dual-eligible and disabled enrollment.

CMS began exercising its authority under the Affordable Care Act (ACA) to non-renew contracts with consistently low Star Ratings in 2016, but the impact of this termination authority is limited in scope. Only a handful of contracts each year have fallen into the band where termination is possible, and some of these companies have higher-performing contracts into which the low-performing contracts could be consolidated. The suspension of this termination authority in the 21st Century Cures Act provides short-term relief for a small number of contracts that may otherwise have received non-renewal notices in February 2017 (effective December 31, 2017).

Implications and action steps for plans are as follows:

- This delay offers a temporary reprieve to a handful of Medicare Advantage plans at risk of termination. Lower-ranked plans forego significant bonus opportunities and tend to grow at slower rates than plans with higher Star Ratings.
- Plan Sponsors that may have been considering consolidating low-performing contracts into higher performing contracts may now abandon or delay any changes.
- The ongoing work on socioeconomic status and dual-eligible status could provide plans an opportunity to engage with CMS and shape the more permanent adjustment.

Requirement to Update Medicare Enrollment Handbook (§ 17003)

The Act also requires the secretary of HHS to update the "Welcome to Medicare" package to include information about the options for receiving benefits under Medicare Parts A through D, after consulting with stakeholders.

The Welcome to Medicare package is often the first document newly eligible beneficiaries receive, and is a key opportunity for beneficiaries to learn about enrollment in Medicare and their option to enroll in Parts C and D. Enrollment errors often result in coverage delays and lifetime premium penalties. Beneficiary advocacy groups believe that updating the package will reduce such errors.

Updates to the package may offer Medicare Advantage plans the opportunity to influence how beneficiaries are first introduced to the Medicare Program and to shape their view of Medicare Advantage in relation to Parts A and B. With a new administration handling development of the package, additional emphasis on Parts C and D in the handbook may drive increased enrollment in those programs.

Medicare Advantage plans should monitor CMS for requests for information or comment regarding updating the package and should consider responding to CMS with advice leveraging their expertise in outreach to and education of beneficiaries.

Restoring the Medicare Advantage Open Enrollment Period (§ 17005)

Another provision of the Act implements changes to Medicare Advantage open enrollment. Currently, a beneficiary enrolled in a Medicare Advantage plan may elect to disenroll from her plan and enroll in Medicare Parts A and B within the first 45 days of a year or, for a newly eligible beneficiary who has enrolled in a Medicare Advantage plan, in the first 45 days of coverage. Changes to other Medicare Advantage plans during this time period are not allowed under current law.

The Act restores a Medicare Advantage open enrollment period similar to the open enrollment period that existed prior to the enactment of the ACA, representing in part a rolling back of one of the ACA's less popular provisions. Under the Act, beginning in 2019, a Medicare Advantage or Part D enrollee will be able to elect to change her enrollment to either another Medicare Advantage Plan or to Medicare Parts A and B within the first three months of the year or, for a newly eligible beneficiary who has enrolled in a Medicare Advantage plan, the first three months of her coverage. One important distinction between this provision and the open enrollment period as it existed prior to the ACA is that this provision does not restrict changing enrollment between Medicare Advantage plans that include drug coverage and those that do not.

The change to open enrollment gives plans an additional three-month opportunity to enroll beneficiaries, but may also introduce administrative complexities associated with mid-year transitions between plans. In preparation for the changes:

- Plans should consider adjusting their enrollment and termination policies for 2019 to accommodate this new enrollment period.
- Plans should monitor for CMS guidance implementing this provision and update their marketing practices for 2019 to align with permissible marketing practices for newly enrolled Medicare Advantage beneficiaries.

Qualified Small Employer HRAs (§ 18001)

The Act also authorizes small employers to make tax-advantaged contributions through individual Health Reimbursement Accounts (Individual HRAs) towards the purchase of individual health insurance coverage by their employees. Currently, such contributions conflict with ACA minimum coverage standards and are penalized under the tax code. The adoption of this policy may represent an acknowledgement that small businesses have not fared well under the ACA, as fewer offer coverage today than prior to the law's enactment.

Individual HRAs represent both a challenge and opportunity for health insurance issuers. The shift of a significant portion of current small group enrollment to the individual market would potentially introduce uncertainty into small group rate setting and expected risk adjustment outcomes. Conversely, such a shift in enrollment to the individual market may assist in stabilizing the current uncertainty in that market. Because small businesses may begin shifting their coverage to the individual market starting in 2017, issuers will have limited opportunities to adapt to this new reality.

Individual HRAs present an opportunity for small businesses to simplify the administration of their health benefits. However, because in most states individual market premiums vary by age and because the Act permits variation in employer contributions based on premiums, small employers should ensure their contributions towards Individual HRAs are structured consistent with applicable federal law including the Age Discrimination in Employment Act (ADEA).

In preparation for this change:

- Issuers should take advantage of all mid-year rate-setting opportunities to adjust rates to align with expected changes in enrollment.
- Issuers should prepare for potential changes to enrollment in their small group plans.
- Issuers should prepare for a potential influx of new members (potentially with lower overall health risks) into their individual market plans.
- Employers wishing to offer Individual HRAs to their employees should consider applicable state and federal employment laws, including the ADEA, when structuring Individual HRA employee contributions.

Seth Schneer, an associate in the Washington, DC, office, also contributed to this article.

FDA: Examining Medical Device Provisions

Vernessa T. Pollard, Veleka Peeples-Dyer, Michael W. Ryan and Vanessa K. Burrows

The US Food and Drug Administration (FDA) related portions of the 21st Century Cares Act, found in title III, establish a streamlined process for the exemption of certain Class I and II devices from the premarket notification requirement and allow for the establishment of revised regulatory standards for accessories to high-risk devices. The law also increases the number of diseases for which the humanitarian device exemption (HDE) may be applicable, aids sponsors of breakthrough devices by expediting the review process and alters FDA's authority to regulate certain types of medical software. Moreover, the device-related provisions enhance transparency with respect to FDA's decision whether to recognize international or national standards, and by giving industry representatives increased opportunities to participate in and influence device classification panel meetings. The legislation contains portions of several bills that were previously introduced, but not advanced by the Senate, including:

- FDA Device Accountability Act of 2015,
- Preventing Superbugs and Protecting Patients Act,
- Advancing Breakthrough Devices for Patients Act of 2016,
- Patient-Focused Impact Assessment Act of 2016, Combination Products Regulatory Fairness Act of 2016,
- Medical Electronic Data Technology Enhancement for Consumers' Health (MEDTECH) Act, and
- FDA and NIH Workforce Authorities Modernization Act.

Overview of the Medical Device Provisions in the Cures Act

The device provisions are generally friendly to device manufacturers, with one notable exception—manufacturers of reusable devices. (Reusable devices came under scrutiny for their association with multi-drug resistant bacteria and a number of patient-to-patient infections linked to cleaning and reprocessing of the devices.) In general, the Cures Act provisions seek to:

- Expedite the review process for breakthrough devices;
- Extend the HDE to devices intended to treat a broader range of conditions;
- Streamline the process for exempting certain devices from the premarket notification requirement;
- Reduce burdens for manufacturers seeking Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived status for in vitro diagnostic (IVD) kits;
- Clarify FDA's authority to regulate medical device software;
- Clarify FDA's requirements for reusable devices, and position regarding when a 510(k) is required to be submitted for a modification to a device already on the market; and
- Enhance transparency in a number of areas, including recognition of international standards and participation in device classification panels.

Why These Provisions Matter

CHANGES TO THE REVIEW AND APPROVAL OR CLEARANCE PROCESS

The expansion of FDA's existing priority review program for breakthrough devices for which there is no approved or cleared device currently on the market will benefit sponsors that receive a breakthrough designation. In addition to the potential benefits associated with the expedited review process, the new law provides that FDA may enter into a binding agreement with breakthrough device sponsors that addresses clinical protocols that could support an application for premarket approval or a 510(k) or de novo submission—and once the agency and a sponsor reach an agreement on trial design, FDA will encounter procedural hurdles if it decides to require changes to the protocol. Changes must be agreed to by both parties or FDA must meet with the sponsor to discuss a substantial scientific issue essential to determining the device's safety or effectiveness and issue a decision that such issue exists.

"The device provisions are generally friendly to device manufacturers, with one notable exception—manufacturers of reusable devices."

Manufacturers of devices that treat or diagnose conditions that affect 8,000 or fewer individuals in the US each year may benefit from the law's expansion of the HDE. Under the HDE, FDA may grant an exemption from effectiveness requirements for devices designed to treat or diagnose rare diseases for which no comparable device is available. The number of the devices distributed under a HDE must not exceed the number of devices reasonably needed to treat, diagnose or cure a population of not more than 8,000 individuals in the United States—prior to the Cures Act, the threshold was 4,000. Diseases that affect between 4,000 and 8,000 individuals in the US each year include tuberculosis and cerebral palsy, according to the National Organization for Rare Disorders. By increasing the potential populations that may be treated by a device available under an HDE, the Cures Act may increase utilization of the HDE pathway, which has historically been low. FDA's issuance of an accompanying guidance may help applicants provide information that will speed up the review process for HDEs, which has historically been lengthy.

Manufacturers of Class I and II devices may benefit from a provision that requires the agency to regularly re-evaluate whether such products should be subject to the 510(k) requirement. For those devices for which FDA decides not to require premarket notification, manufacturers will further benefit from a provision that streamlines the rulemaking requirement for making conforming revisions to applicable regulations. The procedures set forth in the Cures Act potentially expedite, by several years, the effective date of any FDA decision to not require premarket notification. As a result, the Cures Act appears to incorporate by statute the policy that FDA set forth in a 2015 guidance, which explained the agency would not enforce 510(k) requirements for Class I or II devices listed in the guidance, though FDA had not issued a final rule to amend its classification regulations.

REDUCED BURDENS

Sponsors of premarket approval applications may benefit from Congress's renewed emphasis that FDA consider the least burdensome means to meet agency needs when evaluating premarket submissions. Although the Cures Act does not change the standards for premarket approval, the law indicates FDA should consider the role of postmarket information when determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

Manufacturers IVD kits are the beneficiaries of a provision that requires FDA to revise a specific section of an existing guidance on CLIA waiver applications. FDA has the authority to grant a test waived status under CLIA—and therefore make the test eligible for performance in a laboratory operating under a CLIA Certificate of Waiver—if the test is simple and has an insignificant risk of producing an erroneous result. FDA assesses whether a test has an insignificant risk of producing an erroneous result, in part, by evaluating whether the test produces accurate results when used by a waived user. Under

the current version of the guidance, FDA evaluates accuracy by comparing the test's performance when used by a waived user to certain statistical guardrails that may or may not be clinically relevant based on the test's intended use. The Cures Act requires FDA to use a different, potentially less restrictive comparison when evaluating a test's accuracy—*i.e.*, the test's performance when performed by a moderate complexity user. This change will likely require FDA to approve waiver applications for additional IVD kits.

FDA REGULATION OF SPECIFIC DEVICES

The Cures Act contains three provisions aimed at specific devices or accessories. First, manufacturers of certain reusable devices will be required to include validated instructions for use and validation data regarding the cleaning, disinfection and sterilization of such devices. Second, manufacturers of certain types of medical software may benefit from the enhanced regulatory clarity provided by a provision that explicitly excludes certain general software functions from FDA regulation. Third, manufacturers of accessories intended to be used with devices that require premarket approval or a 510(k) submission may benefit from the inclusion of an explicit statutory provision that allows FDA to down-classify accessories based on their intended use, as opposed to the classification of the device with which the accessory is intended to be used.

ENHANCED TRANSPARENCY

Manufacturers that comply with internationally recognized quality requirements may benefit from a new provision that sets forth enhanced procedures with respect to the recognition of such standards. Though the Cures Act does not change the existing process that enables FDA to recognize an international or national standard, the law requires the agency to be transparent in its rationale for recognizing, or declining to recognize, such standards. Under the new law, stakeholders may submit a request for the recognition of all or part of a standard created by an international or national standards organization. FDA must decide whether to recognize all or part of that standard and issue a publicly available rationale for the agency's determination. Although FDA may continue its non-recognition of well-recognized international standards (*e.g.,* ISO 13485), requesters will be able to comprehend and possibly better respond to the agency's concerns once its rationale is made public.

The Cures Act will assist device industry representatives by providing enhanced transparency in the voting membership of device classification panels, which now must include individuals knowledgeable about technology and with clinically relevant expertise. The law does not change existing membership requirements or the types of organizations who may nominate individuals for the panels, but instead permits patients, patient representatives and device sponsors to recommend individuals with appropriate expertise for voting member positions. Industry representatives will be afforded additional opportunities during a panel meeting to correct misstatements, provide clarifying information and respond to questions from the panel.

What Is Required by These Cures Act Provisions

CHANGES TO THE REVIEW AND APPROVAL OR CLEARANCE PROCESS

Section 3051 of the Cures Act gives FDA explicit statutory authority to extend the existing priority review program for breakthrough devices to 510(k)s and *de novo* submissions. (Previously, in a guidance document, FDA extended the priority review program to 510(k) and *de novo* submissions due to the potential public health importance of devices warranting priority review status.) The Cures Act also codifies criteria for determining what constitutes a breakthrough device, and provides specific examples of significant, clinically meaningful advantages that reflect the guidance document.

Section 3052, which expands eligibility for the HDE, requires FDA to issue a draft guidance defining a "probable benefit" to health from the use of the device. To obtain a HDE, the probable benefit to health must outweigh the risk of injury or illness.

Section 3054 requires FDA to identify and list any Class I or II devices that are exempt from the premarket notification requirement and update these lists at least every five years. FDA must publish initial lists of Class I and II devices in the *Federal Register* within 120 and 90 days, respectively, of the

law's enactment. Previously, FDA was not statutorily required to update the list of Class II devices on a regular basis, or publish a list of Class I devices for which premarket notification is not necessary to assure safety and effectiveness, though the agency made a one-time commitment to identify 510(k) exempt devices during the last device user fee reauthorization.

REDUCED BURDENS

Section 3057 requires FDA to issue revised guidance on certain aspects of consideration for designation as a CLIA-waived IVD.

Section 3058 instructs FDA to consider the least burdensome appropriate means necessary in requesting information related to premarket approval applications. The agency's summary of the scientific and regulatory rationale for significant decisions regarding submission or review of reports or applications must now include a statement on FDA's consideration and application of least burdensome requirements. Additionally, FDA employees involved in reviewing premarket submissions must receive training on the least burdensome requirements.

FDA REGULATION OF DEVICES, ACCESSORIES AND SOFTWARE

Section 3059 requires FDA to finalize a draft guidance describing when a manufacturer must submit a 510(k) for a modification or change to a device already on the market. Regulated industry has waited years for a revised guidance, as the current version dates to 1997 (and an earlier update was withdrawn in 2012). The Cures Act requires the agency to finalize the guidance by November 7, 2017.

Section 3060 carves out five types of medical software functions that will not be treated as devices: devices (1) for administrative support (*i.e.*, claims); (2) for maintaining and encouraging a healthy lifestyle, but unrelated to the diagnosis, cure, prevention or treatment of a disease or condition; (3) that serve as electronic patient records if the records are part of certified health information technology; (4) for transferring, storing, converting or displaying clinical laboratory test or other data and results; and (5) for displaying, analyzing or printing medical information (other than medical images, signals from IVDs or signal acquisition systems), supporting or providing recommendations about prevention, diagnosis or treatment, if the health care professional may independently review the basis for the recommendations and is not intended to rely primarily on the recommendations to diagnose or treat patients. However, FDA may regulate some of the exempted software if the agency makes a finding that the software function would be reasonably likely to have serious adverse health consequences. To regulate exempted software, FDA must publish its finding, the agency's rationale, and a proposed order; accept comments; and publish a final order.

ENHANCED TRANSPARENCY

Section 3053 requires FDA to train its employees on the concept and use of recognized national or international standards for the purpose of meeting premarket submission or other requirements. FDA must also review and, if necessary, update existing or previously issued guidance and standard operating procedures that identify the principles for recognizing, or withdrawing recognition of, standards.

Under existing law, FDA secures recommendations regarding the classification of devices into Class I, II or III from a panel of experts. Section 3055 adds a new membership requirement for the classification panels to ensure the panels have "adequate expertise," which the Cures Act defines as two or more voting members with a specialty or other expertise clinically relevant to the device under review and at least one voting member knowledgeable about the device's technology.

Action Steps for Device Manufacturers and Other Stakeholders

Sponsors interested in the breakthrough device pathway should begin to evaluate the extent to which existing data enables the sponsor to make a compelling argument under the criteria listed in Section 3051. If such data is lacking, sponsors should take steps to generate such data and arguments.

Device manufacturers should begin tracking the times when they believe FDA has required an unreasonable amount or type of information in order to support an application and consider invoking the new least burdensome review provision. Although FDA is not required to accept less data than is currently needed to support a submission, a sponsor of a device can use the language added by Section 3058 as

leverage in negotiations with FDA over the amount and types of information required.

Finally, insofar as many of the above provisions require FDA to take steps to implement the changes envisioned by Congress, stakeholders should consider participating in public meetings or other outreach efforts by FDA to develop or revise applicable guidance documents.

FDA: Streamlining Regulations for Clinical Research

Veleka Peeples-Dyer, Vernessa T. Pollard, Michael W. Ryan, Vanessa K. Burrows and Shelby Buettner

Title III of the 21st Century Cures Act includes portions of the FDA Device Accountability Act of 2015, Promoting Biomedical Research and Public Health for Patients Act, and FDA and NIH Workforce Authorities Modernization Act. These bills were introduced, but not advanced, by the US Senate.

The prevalence of precision medicine, innovative cures and individualized patient treatments has caused FDA and other regulators to rethink traditional approaches to clinical research. Recent FDA initiatives to encourage adaptive clinical trial designs for novel therapies may signal a move toward greater flexibility regarding the types of clinical evidence and data that is adequate to support a product approval. The clinical trial portions of this legislation focus on streamlining clinical research by harmonizing human subject research protections and informed consent requirements across agencies, so that FDA's human subject regulations are more in line with the human subject regulations of the US Department of Health and Human Services (HHS), which are known as the Common Rule. The bill also offers researchers the flexibility to use non-local institutional review boards (IRB) for investigational and humanitarian use devices and novel clinical trial designs and data in the drug and biological products approval and licensure processes.

3021. Novel Clinical Trial Designs

The Cures legislation requires FDA to hold a public meeting and issue guidance to assist sponsors in incorporating complex adaptive and other novel trial designs into proposed

clinical protocols and applications for new drugs and biological products. Among other items, the new guidance must address the use of such designs to demonstrate the safety and effectiveness of new drugs under the substantial evidence standard (evidence of adequate and well-controlled investigations) for FDA approval of new drugs. The guidance must also address how to submit information from modeling and simulations. This future guidance has the potential to significantly broaden the methodologies of analysis and data that may be used to support the approval and licensure of new products.

In the provision, Congress does not explicitly state whether it intends for the agency to finalize the policies set forth in the 2010 adaptive design draft guidance as-is, or if it expects the agency to make meaningful revisions to that document. However, this section of the legislation suggests that Congress expects FDA to be more flexible in evaluating the evidence of safety and effectiveness to support new drug and biological product applications. Companies with applications pending before the agency (or preparing to submit such applications) should consider leveraging the legislative language to support arguments that safety and effectiveness can be evaluated with more flexible and/or modern trial designs than FDA has traditionally required.

Additionally, sponsors and other stakeholders should consider attending the public meeting and submitting written or oral comments to inform FDA's development of the guidance.

3023. Protection of Human Research Subjects

Effecting a change long sought by researchers, the legislation requires the HHS secretary to harmonize differences between HHS and FDA regulations for the protection of human subject (generally) and vulnerable populations (specifically). The harmonization effort may modernize the regulations to facilitate multi-site and cooperative research projects, avoid regulatory duplication and delays, protect vulnerable populations, and encourage community engagement. Additionally, the legislation encourages sponsors of research that is subject to both HHS and FDA human subject regulations to use a joint or centralized IRB review process. This provision may benefit multi-site trials by consolidating the IRB process.

> "Sponsors should re-examine their plans for trials and centralize the IRB process insofar as use of a local IRB was intended solely to address FDA requirements."

This section streamlines the process by which human subject research may be reviewed and conducted. This harmonization effort will likely impact the current efforts to amend the Common Rule, which were outlined in a 2015 notice of proposed rulemaking. However, the proposed rulemaking may serve as a guidepost for the effort. For example, the proposed rulemaking would require that cooperative research or multi-site studies rely on a single IRB, with limited exceptions, which is consistent with the flexibility proposed under certain circumstances in Section 3056 of the Cures legislation (described below). The extent to which HHS will change any individual provision is unclear at this time, but potential targets are revision of the types of studies that require IRB review and oversight, allowable IRB exemptions, inconsistent definitions (*e.g.,* research, human subject), and various aspects of the informed consent process. For example, harmonization efforts may make it easier for sponsors to obtain and use retrospective analyses of de-identified data, which have historically been exempt from the informed consent requirement under the Common Rule but not expressly exempt under FDA regulations. The possibility of establishing an analogous exemption under FDA requirements may significantly increase the extent to which sponsors rely on such analyses to support product development and other activities. Entities that perform human subject research should monitor HHS's efforts to consult with stakeholders and the *Federal Register* for additional opportunities to comment on the harmonization process, rulemakings and guidance, as this section arguably provides an opportunity to broaden the exceptions to when informed consent is required for FDA-regulated clinical investigations.

3024. Informed Consent Waiver or Alteration for Clinical Investigators

The legislation allows FDA's informed consent requirements to be waived or altered for trials of investigational drugs or devices if the proposed clinical tests pose no more than minimal risk to the human subjects and include appropriate safeguards to protect the rights, safety and welfare of the subjects. The legislation does not define the phrase "no more than minimal risk" and does not cross-reference any existing HHS or FDA regulations or guidance to provide insight as to how such language should be interpreted by the FDA. Although the phrase is not defined in the US Code, FDA has defined in 21 C.F.R. § 50.52 what constitutes a clinical investigation involving greater than minimal risk to children. Under that regulation, an IRB must find that (1) the risk is justified by the anticipated benefit to the subjects; (2) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (3) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in a separate FDA rule. The FDA's interpretation of the phrase and the language on the "appropriate safeguards" required to protect human subjects will likely require a separate rulemaking or guidance, as the broad statutory language "no more than minimal risk" could be construed in many different ways.

To the extent that FDA's interpretation of "no more than minimal risk" tracks existing HHS regulations on the protection of human research subjects, this section could potentially harmonize FDA's informed consent requirements with existing HHS and National Institutes of Health (NIH) requirements under the Common Rule. For example, in 45 C.F.R. § 46.102, HHS defines "minimal risk" as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Additional HHS regulations discuss "minimal risk" in the context of research involving not greater than minimal risk to children, research involving greater than minimal risk that presents the prospect of direct benefit to the individual subjects, and research involving greater than minimal risk and no prospect of direct benefit, but that is likely to yield generalizable knowledge about the subject's disorder or condition. FDA may examine the protections in these HHS regulations on "minimal risk" and "greater than minimal risk" to establish appropriate safeguards.

Depending on FDA's interpretation of the phrase "no more than minimal risk," stakeholders that perform, participate in, and/or evaluate investigational drug and device human subject research may have greater freedom to pursue trial designs that were previously impractical under FDA regulations. This legislative change could provide new opportunities for sponsors to use "big data," in particular in retrospective analyses of de-identified data, in submissions to the agency, as such analyses arguably pose no more than a minimal risk to patients.

3056. Institutional Review Board Flexibility

The Cures legislation strikes references to "local" IRBs in the investigational and humanitarian device exemptions, which exempt such devices from requirements including labeling, registration, premarket approval, recordkeeping and reporting. Sponsors, investigators and others involved in a device trial or other device use (*e.g.,* diagnosis or treatment) within the scope of the exemptions will now be allowed to engage a centralized or other non-local IRB for review and approval. This section is consistent with the trend toward centralization of IRB operations and avoidance of duplication of review, especially as associated with multi-site trials.

Sponsors should re-examine their plans for trials and centralize the IRB process insofar as use of a local IRB was intended solely to address FDA requirements. This legislative change may ease the process of beginning a clinical trial and addressing ongoing oversight of a trial. Stakeholders—including investigators, health care providers and medical centers—that administer trials or perform patient services with investigational or humanitarian devices may need to modify existing practices, policies and procedures to allow for review by non-local IRBs.

FDA: Clarifying Drug Provisions

Vernessa T. Pollard, Veleka Peeples-Dyer, Michael W. Ryan, Vanessa K. Burrows and Anisa Mohanty

The 21st Century Cures Act includes portions of five previously introduced bills that were not advanced by the Senate relating to FDA regulation of drugs, biologics and combination products, including:

- Advancing Targeted Therapies for Rare Diseases Act of 2016,
- Patient-Focused Impact Assessment Act of 2016,
- Promise for Antibiotics and Therapeutics for Health (PATH) Act,
- Combination Products Regulatory Fairness Act of 2016, and

- FDA and NIH Workforce Authorities Modernization Act.

These provisions appear in title III of the new legislation.

Overview of the Drug Provisions in the Cures Act

The drug provisions of the Cures Act are generally friendly to sponsors and manufacturers, and largely impose additional requirements on FDA. In general, the Cures Act provisions seek to:

- Expedite the review process for certain drugs,
- Facilitate the recognition of drug outcome measures,
- Encourage the consideration of data beyond that produced in randomized clinical trials to support approval,
- Create a new priority review voucher (PRV) for material threat medical countermeasures,
- Extend the current rare pediatric disease PRV program,
- Clarify the scope of permissible dissemination of health care economic information (HCEI) by manufacturers, and
- Require manufacturer publication of expanded access policies.

Why These Provisions Matter

CHANGES TO THE REVIEW AND APPROVAL PROCESS GENERALLY

The Cures Act does not modify the statutory standard for the approval of a new drug or biologic. As outlined below, however, the Cures Act included several provisions that may impact the types of evidence FDA will consider when deciding whether individual products meet the statutory standard.

The codification of FDA's current guidance-based qualification process for Drug Development Tools (DDT)—*e.g.*, biomarkers, clinical outcome assessments, and other methods, materials or measures—may benefit drug developers and biomedical research consortia, promote drug innovation and expedite review of regulatory applications. The Cures Act requires FDA to create a process by which a sponsor, consortia or other requestor can seek to qualify a DDT for its proposed context of use. A DDT is qualified if FDA determines its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review. Qualified DDTs may be used to support or obtain approval or licensure of a drug or biologic, or to support an investigational use. Companies developing drugs for conditions that lack well-established outcome measures, or for which existing measures fail to assess critical performance parameters, may benefit from an established process for the qualification of DDTs. FDA has also stated that companies can pool resources and data to develop a DDT, which may reduce the cost associated with development and recognition of such measures.

"The Cures Act included several provisions that may impact the types of evidence the FDA will consider when deciding whether individual products meet the statutory standard."

Notwithstanding objections from certain consumer advocacy groups, the statute also requires FDA to establish a program to evaluate the potential use of "real world evidence"—*i.e.*, data regarding the usage or potential benefits or risks of a drug that is derived from sources other than randomized clinical trials—in support of applications for new indications for FDA-approved drugs and/or to support or satisfy post-approval marketing requirements. FDA must, in consultation with industry, advocacy groups and others, draft a framework for the program's implementation, and then implement the program within two years of the law's enactment.

Drug and biologics developers may also benefit from a provision that allows FDA to rely on a "qualified data summary"—a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication—to support the approval of applications for new

uses of previously approved products. A qualified indication is an indication for a drug that FDA determines is appropriate for

summary level review; the Cures Act does not, however, provide guidance on how FDA should assess whether an indication is "appropriate" for such review. A supplemental application is eligible for summary level review if (1) there is existing data available and acceptable to FDA that demonstrates the safety of the drug; and (2) data used to develop the qualified data summaries are submitted to FDA as part of the supplemental application.

CHANGES TO THE REVIEW AND APPROVAL PROCESS FOR CERTAIN DRUGS

Sponsors of drugs that FDA designates as regenerative advanced therapies (RAT)—*e.g.*, cell therapies, therapeutic tissue engineering products, human cell and tissue products—may benefit from a provision authorizing priority review and accelerated approval. For a sponsor's drug to be designated a RAT by FDA, the drug must be intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that the drug has the potential to address unmet medical needs for such disease or condition. A new drug application (NDA) or biologics license application (BLA) for a RAT may be eligible for accelerated approval through reliance on surrogate or intermediate endpoints reasonably likely to predict long term clinical benefit or data from a meaningful number of sites.

Similarly, sponsors of antibacterial and antifungal drugs intended to treat serious or life-threatening infections in a limited population of patients with unmet needs may benefit from the creation of a new "limited population" approval pathway. The new pathway is designed to expedite approval of these drugs without requiring large-scale clinical trials or testing in specific populations. The labeling and advertisements for such drugs must contain a statement that the drug's safety and effectiveness has only been demonstrated with respect to a "limited population," and the promotional materials for such drugs must be submitted to FDA prior to dissemination. FDA Commissioner Robert Califf explained that the drugs are to be "used narrowly … while additional evidence is generated to assess safety and effectiveness for broader use."

Sponsors of genetically targeted or variant protein targeted drugs—drugs for the treatment of rare diseases or serious or life-threatening conditions which, respectively, may modulate the function of a gene or modulate the function of a product of a mutated gene—may benefit from a provision that enables FDA to permit a sponsor to rely on data previously developed and submitted by the sponsor (or another sponsor, with the appropriate right of reference) as part of an approved NDA or BLA. The law is intended to address the challenge of conducting clinical trials in small populations of patients, especially subgroups of patients with the same disease or condition but different genetic mutations. To be eligible under this provision, drugs must incorporate or use the same or similar technology as the drug in the previously approved application.

PRIORITY REVIEW VOUCHER PROGRAMS

Sponsors of material threat medical countermeasures may benefit from the law's creation of a new Priority Review Voucher (PRV) program, which entitles the holder of a PRV to expedited FDA review of a subsequent drug product application within six months, which is four months faster than the standard review process. A sponsor would receive a PRV upon approval of an application for a material threat medical countermeasure application that (1) prevents or treats harm from biological, chemical, radiological or nuclear agents that present a material threat against the US population sufficient to affect national security or (2) mitigates, prevents or treats harm from a condition that may result in adverse health consequences or death, and may be caused by administering a drug or biologic against an agent that presents a national security threat. Like other PRV programs, holders must notify FDA before using the PRV, and the program sunsets on a date certain (October 1, 2023). PRVs issued under this program are also transferable, which, given the robust market for PRVs issued under other authorities, may make the program a significant incentive toward the development of "material threat" medicines.

Sponsors of drugs for rare pediatric diseases may benefit from the extension of the corresponding PRV program through September 30, 2020.

DISSEMINATION OF HEALTH CARE ECONOMIC INFORMATION

Manufacturers and others who disseminate "health care economic information" (HCEI) related to drugs and devices may benefit from the clarification and expansion of permissible communications. HCEI will not be considered false or misleading labeling if it (1) is disseminated to persons to whom such information may be communicated; (2) relates to approved indications and is based on competent and reliable scientific evidence; and (3) includes a "conspicuous and prominent statement describing any material differences" between HCEI and FDA-approved labeling. As compared with previous interpretations of labeling, advertising and misbranding provisions in the Federal Food Drug and Cosmetic Act (FFDCA) which restricted the content and contexts in which HCEI could be disseminated, the Cures Act provides greater flexibility. The Cures Act expands the audience to whom HCEI may be communicated (to include payors and similar entities with expertise in health care economic analysis that select drugs for coverage or reimbursement), expands the types of analysis that may be shared (to include clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis, as well as separate or aggregated consequences from the represented health outcomes), and liberalizes the previous requirement that HCEI "directly relate" to approved indications (now HCEI must only "relate" to such indications). The provision does not apply, however, to any analysis that relates only to unapproved indications.

SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA

Holders of existing NDAs and BLAs must remove susceptibility test interpretive criteria, which characterize the susceptibility of bacteria or other microorganisms to the antimicrobial drug tested and categorize a drug's susceptibility (*i.e.*, susceptible, intermediate, resistant), from approved drug labeling and replace the information with a reference to the newly-mandated FDA interpretive criteria website. Similarly, antimicrobial drugs approved after the website is created must reference the website in their labeling in lieu of susceptibility test interpretive criteria. The statute requires FDA to include certain disclaimers about the limits of safety and efficacy of such drugs, the clinical significance of susceptibility information and approved product labeling, on the website. Antimicrobial drug manufacturers and others may benefit from a provision permitting FDA to consider information provided by "interested third parties" when evaluating new or updated susceptibility test interpretive criteria standards.

COMBINATION PRODUCTS

In response to complaints that FDA improperly regulated certain combination products as drugs or biologics based on an overly restrictive application of the "primary mode of action" test, the Cures Act prohibits FDA from determining that a combination product's primary mode of action is that of a drug or biologic solely because the combination product has *any* chemical action within or on the human body. Chemical action in the body is a statutory concept that distinguishes a drug or biologic from a medical device. The Cures Act requires FDA to determine how a combination product will be regulated based on a new statutory definition of "primary mode of action," which focuses on the single mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

What Is Required by These Cures Act Provisions

STAKEHOLDER-RELATED REQUIREMENTS

Manufacturers or distributors of investigational drugs for serious diseases or conditions must make publicly available their expanded access policies on requests for such drugs within 60 days of the law's enactment or the initiation of a phase 2 or phase 3 study of an investigational drug, whichever date is later.

REQUIREMENTS IMPOSED ON FDA

FDA must issue guidance on:

- The collection and use of patient experience data— data intended to provide information about patients' experiences with a disease or condition—in drug development (draft guidance due 18 months after enactment);
- The process for qualification of DDTs (draft guidance due three years after enactment);
- The circumstances under which drug sponsors and FDA may rely on real world evidence (draft guidance due five years after enactment);

- Pre-submission interactions with sponsors developing combination products and submissions of information with meeting requests (final guidance due four years after enactment); and
- The criteria, processes and considerations for demonstrating safety and effectiveness of limited population antibacterial and antifungal drugs (draft guidance due 18 months after enactment).

The agency may also issue updated guidance and regulations within one year of developing standards to support the development, evaluation and review of regenerative medicine therapies and RATs.

FDA must issue the following reports assessing:

- The use of patient experience data in regulatory decision-making (by June 1 of 2021, 2025 and 2031);
- The qualification process for DDTs (five years after enactment);
- Approval of RATs, as well as the number of applications for which FDA granted accelerated approval or priority review (by March 1 of each year);
- Approvals of antibacterial or antifungal drugs under the limited population pathway (every two years); and
- The implementation of the new statute on the susceptibility test interpretive criteria (two years after enactment).

The Cures Act also requires FDA to take other actions:

- Issue a draft framework for implementation of a program to evaluate real world evidence;
- Post information on the review of supplemental applications that rely on qualified data summaries;
- Develop standards and consensus definitions related to the development, evaluation and review of regenerative medicine therapies and RATs;
- Provide advice to sponsors of limited population drugs on data needed for approval;
- Identify, list and update susceptibility test interpretive criteria and susceptibility test interpretive criteria standards on the new FDA interpretive criteria website; and
- Post guidelines of best practices for drug safety surveillance using the FDA Adverse Event Reporting System and criteria for public posting of adverse event signals.

ACTION STEPS FOR DRUG MANUFACTURERS AND OTHER STAKEHOLDERS

Manufacturers should re-evaluate the extent to which they hold promising data but set aside certain FDA submissions due to an inability to run the randomized controlled trials that would likely have been required. Insofar as one or more of the additional sources of evidence recognized in the Cures Act could support an application, sponsors should consider citing the Cures Act in negotiations with the agency regarding the amount and type of evidence required to support a successful application.

Manufacturers should also evaluate the extent to which new drugs or new indications for old drugs may be candidates for an expedited review pathway or a PRV, and evaluate the extent to which they have the data to support such applications or can generate the required information. Sponsors of genetically targeted drugs and variant protein targeted drugs should consider what previously submitted data may be used in support of subsequent NDAs and BLAs.

With regard to marketing and labeling, manufacturers should re-evaluate whether the relaxed restrictions on HCEI might make it more feasible to proactively address payor and other reimbursement issues that they previously declined to discuss due to regulatory concerns.

Finally, insofar as many of the above provisions require FDA to take steps to implement the changes envisioned by Congress, stakeholders such as manufacturers, clinical trial sponsors, academic institutions, clinicians, industry organizations and standard setting organizations should consider participating in public meetings or other outreach efforts by FDA to develop or revise applicable standards, guidance documents and regulations.

Office Locations

BOSTON
28 State Street
Boston, MA 02109
USA
Tel: +1 617 535 4000
Fax: +1 617 535 3800

BRUSSELS
Avenue des Nerviens 9-31
1040 Brussels
Belgium
Tel: +32 2 230 50 59
Fax: +32 2 230 57 13

CHICAGO
227 West Monroe Street
Chicago, IL 60606
USA
Tel: +1 312 372 2000
Fax: +1 312 984 7700

DALLAS
2501 North Harwood Street, Suite 1900
Dallas, TX 75201
USA
Tel: +1 214 295 8000
Fax: +1 972 232 3098

DÜSSELDORF
Stadttor 1
40219 Düsseldorf
Germany
Tel: +49 211 30211 0
Fax: +49 211 30211 555

FRANKFURT
Feldbergstraße 35
60323 Frankfurt a. M.
Germany
Tel: + 49 69 951145 0
Fax: + 49 69 271599 633

HOUSTON
1000 Louisiana Street, Suite 3900
Houston, TX 77002
USA
Tel: +1 713 653 1700
Fax: +1 713 739 7592

LONDON
Heron Tower
110 Bishopsgate
London EC2N 4AY
United Kingdom
Tel: +44 20 7577 6900
Fax: +44 20 7577 6950

LOS ANGELES
2049 Century Park East, 38th Floor
Los Angeles, CA 90067
USA
Tel: +1 310 277 4110
Fax: +1 310 277 4730

MIAMI
333 SE 2nd Avenue, Suite 4500
Miami, FL 33131
USA
Tel: +1 305 358 3500
Fax: +1 305 347 6500

MILAN
Via dei Bossi, 4/6
20121 Milan
Italy
Tel: +39 02 78627300
Fax: +39 02 78627333

MUNICH
Nymphenburger Str. 3
80335 Munich
Germany
Tel: +49 89 12712 0
Fax: +49 89 12712 111

NEW YORK
340 Madison Avenue
New York, NY 10173
USA
Tel: +1 212 547 5400
Fax: +1 212 547 5444

ORANGE COUNTY
4 Park Plaza, Suite 1700
Irvine, CA 92614
USA
Tel: +1 949 851 0633
Fax: +1 949 851 9348

PARIS
23 rue de l'Université
75007 Paris
France
Tel: +33 1 81 69 15 00
Fax: +33 1 81 69 15 15

ROME
Via A. Ristori, 38
00197 Rome
Italy
Tel: +39 06 462024 1
Fax: +39 06 489062 85

SEOUL
18F West Tower
Mirae Asset Center1
26, Eulji-ro 5-gil, Jung-gu
Seoul 04539
Korea
Tel: +82 2 6030 3600
Fax: +82 2 6322 9886

SHANGHAI
MWE China Law Offices
Strategic alliance with
McDermott Will & Emery
28th Floor Jin Mao Building
88 Century Boulevard
Shanghai Pudong New Area
P.R.China 200121
Tel: +86 21 6105 0500
Fax: +86 21 6105 0501

SILICON VALLEY
275 Middlefield Road, Suite 100
Menlo Park, CA 94025
USA
Tel: +1 650 815 7400
Fax: +1 650 815 7401

WASHINGTON, DC
The McDermott Building
500 North Capitol Street, NW
Washington, DC 20001
USA
Tel: +1 202 756 8000
Fax: +1 202 756 8087

McDermott
Will & Emery

Boston Brussels Chicago
Dallas Düsseldorf Frankfurt Houston London
Los Angeles Miami Milan Munich
New York Orange County Paris Rome
Seoul Silicon Valley Washington, DC

Strategic alliance with MWE China Law Offices (Shanghai)

www.mwe.com