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Client Alert

Medicare, Medicaid Payment Policies, Fraud Authorities Enacted as Part of 21st Century Cures Act

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On December 13, 2016, President Obama signed into law the 21st Century Cures Act (Cures Act). While much of the focus has been on policies intended to accelerate drug and device development and approval, the Cures Act also includes numerous provisions impacting the Medicare and Medicaid programs, such as Medicare long-term care hospital (LTCH), infusion drug reimbursement, and durable medical equipment (DME) policies, among many others. Furthermore, the Cures Act once again expands the federal government's fraud and abuse authorities by adding new penalties for various offenses involving Department of Health and Human Services (HHS) grants.

This Client Alert focuses on the major Medicare and Medicaid provisions of the Cures Act. The drug and device development and approval provisions will be addressed in a separate alert. Our recent blog post examined additional provisions in the Cures Act that address mental health and substance abuse policies and fund programs to combat opioid abuse.

MEDICARE POLICY AND PAYMENT PROVISIONS

Medicare Reimbursement for Infusion Drugs – ASP Plus 6 Percent (Section 5004)

Under current law, reimbursement for most Medicare Part B drugs is set at the average sales price (ASP) plus 6 percent. Medicare Part B drugs infused through DME are exempt from this provision and are instead reimbursed at 95 percent of the average wholesale price (AWP) for such drug in effect on October 1, 2003.

The Cures Act subjects drugs infused through DME to the ASP plus 6 percent payment methodology effective January 1, 2017. According to a summary prepared by the House Ways and Means and Energy and Commerce Committees, this "change is based on findings from the HHS [Office of Inspector General (OIG)] which found that the current payment methodology – based on manufacturer sticker prices that were in effect in 2003 – currently over pays some drugs while underpaying for others."

This section also excludes DME infusion drugs from the DME competitive bidding program.

The Congressional Budget Office (CBO) estimates that this provision will save $260 million over five years (2017 – 2021) and $660 million over 10 years (2017 – 2026).

Medicare Coverage of Home Infusion Therapy (Section 5012)

The Cures Act adds Medicare coverage of home infusion therapy, effective January 1, 2021. Home infusion therapy is defined as:

- Professional services, including nursing services, furnished according to a plan of care established by a physician in coordination with the furnishing of home infusion drugs; and
- Training and education (not otherwise paid for as DME), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

For purposes of this provision, "home infusion drug" means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, through a DME pump in the individual's home. The term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. Home infusion therapy will be excluded from home health services under this provision.

A qualified home infusion therapy supplier includes a pharmacy, physician, or other provider or supplier licensed by the state that:

- Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;
- Ensures the safe administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;
- Is accredited by a designated organization (as established by the Cures Act); and

- Meets other requirements established by the Secretary.

The Secretary is directed to implement a *per diem* payment system under which a single payment is made to a qualified home infusion therapy supplier for such services, subject to certain limitations and adjustments. The Secretary also is authorized to apply prior authorization requirements for home infusion therapy services.

Development of Medicare HCPCS Version of MS–DRG Codes for Similar Hospital Outpatient Services (Section 15001)

The Cures Act requires the Secretary to develop a crosswalk between Medicare inpatient and outpatient hospital codes for at least 10 surgical procedures by January 1, 2018. That is, the Secretary must establish hospital outpatient Healthcare Common Procedure Classification System (HCPCS) versions of inpatient Medicare Severity-Diagnosis Related Group (MS-DRG) that are based on International Classification of Disease (ICD) codes. The Secretary must make the HCPCS MS-DRG definitions manual and software available for public use without charge on the Centers for Medicare & Medicaid Services (CMS) website. The Secretary is directed to consult with the MedPAC and consider MedPAC research in this area.

While this provision does not modify Medicare payment policy for the selected surgical procedures, MedPAC research in this area points out that Medicare payment for short inpatient stays is generally much greater than for similar outpatient stays, and that these inpatient short stays are highly profitable for hospitals. Therefore, the availability of codes that could be used in either the inpatient or outpatient setting could eventually facilitate adoption of payment policies fostering more parity in reimbursement.

Proxy for Beneficiary Socio-Economic Status Adopted in the Medicare Hospital Readmission Program (Section 15002)

The Cures Act modifies the Hospital Readmissions Reduction Program to add a transitional adjustment factor for dual-eligible individuals to serve as a proxy for socio-economic status, applicable to discharges beginning in fiscal year 2019. The Secretary must implement this provision on a budget-neutral basis and without imposing additional reporting requirements on hospitals. In promulgating implementing regulations, the Secretary may consider the use of V or other ICD codes for removal of readmissions classified/related to transplants, end-stage renal disease (ESRD), burns, trauma, psychosis, or substance abuse. Furthermore, MedPAC must conduct a study regarding overall hospital readmissions and whether such readmissions are related to any changes in outpatient and emergency services furnished.

Regulatory Relief for Long-Term Acute Care Hospitals (Sections 15004 -15010)

The Cures Act includes, with some modifications, a number of LTCH provisions that were incorporated from H.R. 5713, the "Sustaining Healthcare Integrity and Fair Treatment Act of 2016," or "SHIFT Act," which passed the House in September but was not taken up by the Senate.

Most significant is a provision that delays full implementation of the "25 Percent Rule." Under the 25 Percent Rule, an LTCH is allowed to admit up to 25 percent of its patients from a single general acute care hospital; for patients admitted past the 25 percent threshold, an LTCH faces a significant Medicare reimbursement reduction. Current law has precluded CMS from fully implementing the 25 Percent Rule for freestanding LTCHs for cost reporting years beginning before July 1, 2016, and for LTCH hospitals-within-hospitals (HIHs) for cost reporting years beginning before October 1, 2016. The SHIFT Act would have delayed full implementation for nine months until July 1, 2017, but the Cures Act prohibits full implementation of the 25 Percent Rule for both freestanding LTCHs and LTCH HIHs for discharges occurring on or after October 1, 2016 until October 1, 2017.

The Cures Act also provides relief from certain other LTCH payment policies for a limited number of LTCHs with special circumstances. First, it eliminates the exception to the statutory exclusion of site-neutral and Medicare Advantage patients from the average-length-of-stay (ALOS) calculation for newer LTCHs, so that the ALOS calculation methodology will be the same for all LTCHs. Second, it creates a temporary exception to the application of the site-neutral payment policy for certain LTCHs categorized as spinal cord specialty hospitals, and extends an exception to that policy for certain severe wound discharges from grandfathered LTCH HIHs. Third, the Cures Act removes certain cancer hospitals specializing in neoplastic disease (so-called "subclause (II)" LTCHs) from their classification as LTCHs, and provides for cost-based reimbursement for such hospitals. Fourth, the Cures Act adds a "mid-build" exception to the existing moratorium on LTCH bed expansions; the projected cost of the new exception is offset by increasing the monetary outlier threshold for LTCHs discharges, thereby reducing LTCH outlier payments.

Off-Campus Provider-Based Facilities (Sections 16001 and 16002)

The Cures Act amends the Medicare site-neutral payment limits for certain off-campus provider-based

facilities that were adopted in the Bipartisan Budget Act of 2015 (Bipartisan Budget Act). Since enactment of the Bipartisan Budget Act, hospitals have objected to the law's reduction in Medicare payment for services rendered in new off-campus provider-based facilities. Under the CMS final rule implementing the Bipartisan Budget Act, new off-campus provider-based facilities will be paid under the Medicare physician fee schedule (PFS), rather than the (generally higher-paying) hospital outpatient prospective payment system (OPPS), effective for services provided on or after January 1, 2017 (other than services furnished by a dedicated emergency department). The Act addresses some of these concerns by extending grandfather protection to certain off-campus projects that were under development when the Bipartisan Budget Act of 2015 was enacted.

First, the Cures Act retroactively exempts from the site-neutral payment any new off-campus outpatient facility if the hospital has voluntarily submitted a provider-based attestation to CMS before December 2, 2015. Existing law only exempted from the site-neutral payment policy those hospital services furnished to Medicare beneficiaries at an off-campus outpatient facility on or before November 2, 2015. This exemption applies to a small number of hospital off-campus facilities that were under development and nearly complete when the Bipartisan Budget Act was adopted. Further, it exempts such facilities from the site-neutral payment limit only during calendar year 2017. The site-neutral limits will apply to these facilities beginning in 2018.

A second exemption applies to hospital services furnished in certain off-campus facilities on or after January 1, 2018, if the hospital had a "binding written agreement with an outside unrelated party for the actual construction" of the off-campus facility before November 2, 2015. To be eligible for this exemption, the hospital must: (1) file a provider-based attestation for the off-campus outpatient facility within 60 days of the date of the enactment of the Act (December 13, 2016), (2) submit a certification to CMS within 60 days of the date of the enactment stating that the hospital had the required binding written construction agreement, and (3) add the off-campus outpatient facility to the hospital's Medicare enrollment form. For those hospitals eligible for this exemption, services provided after November 2, 2015 will continue to be paid at the lower rate established by CMS until January 1, 2018, when such services will again be paid at OPPS rates.

A third exemption applies to cancer hospitals that are excluded from the Medicare prospective payment system. In order for a cancer hospital to qualify for the exemption, the hospital must attest that the relevant off-campus provider-based facility either submitted a provider-based attestation to CMS (1) before December 13, 2016, in the case of a facility that met the provider-based requirements after November 1, 2015 and December 13, 2016; or (2) not later than 60 days after the date the facility meets the provider-based requirements in the case of a facility that meets such requirements after December 13, 2016.

Treatment of Eligible Professionals in ASCs for Meaningful Use and MIPS (Section 16003)

To be considered a meaningful user of certified electronic health records (EHR) technology (CEHRT) and avoid penalty under the Medicare EHR Incentive Program, physicians must furnish at least 50 percent of their patient encounters in a setting that uses CEHRT. The meaningful use program sunsets at the end of 2018 and transitions to the new Merit-based Incentive Payment System (MIPS) program established by MACRA.

In light of a lack of availability of CEHRT products in the ambulatory surgical center (ASC) setting, the Cures Act temporarily exempts physicians who furnish substantially all of their Medicare services at ASCs from related payment penalties for not being meaningful EHR users. The determination of applicability of this provision will be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services. This exclusion ends three years after the Secretary determines, through notice and comment rulemaking, that certified EHR technology applicable to the ASC setting is available.

Direct Supervision Requirements in Critical Access Hospitals (Section 16004)

The Cures Act provides an additional one-year extension (through 2016) of the current enforcement moratorium on direct supervision requirements for outpatient therapeutic services in critical access hospitals. The Act also directs MedPAC to report on the effect of the extension of the enforcement instruction on beneficiary access to health care and quality of care, along with its economic impact and impact upon hospital staffing needs.

Locum Tenens Arrangements for Physical Therapists (Section 16006)

The Cures Act 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* (substitute therapist) arrangements for Medicare payment purposes under the same rules that apply to physician *locum tenens* arrangements. Under this provision, physical therapists in such designated areas will be able to retain substitute therapists to take over their practices when the originating therapist is absent

(e.g., because of illness, pregnancy, vacation, or continuing education). The originating therapist will submit the claim, receive the Part B payment, and pay the *locum tenens* for his/her services on a *per diem* or similar fee-for-time basis in conformance with established Medicare rules. The Secretary must implement this provision for services furnished beginning no later than six months after enactment.

Adjustments to Medicare DMEPOS Fee Schedules Based on Competitive Bidding Pricing (Sections 16005, 16007, and 16008)

As previously reported, the ACA mandated that CMS use pricing information from competitive bidding to adjust certain DME, prosthetics, orthotics, and supplies (DMEPOS) fee schedule amounts for items furnished in areas where the competitive bidding program (CBP) is *not* implemented. CMS adopted highly technical regulations to implement these adjustments, which were adopted in two steps:

- For the period January 1, 2016 through June 30, 2016, CMS based fee schedule amounts on a blend of 50 percent of the fee schedule amount that would have gone into effect on January 1, 2016 if not adjusted based on information from the CBP, and 50 percent of the adjusted fee schedule amount.
- Beginning July 1, 2016, CMS implemented new fee schedules reflecting 100 percent of the adjusted fee schedule amounts and incorporating data from the most recent round of competitive bidding.

According to CMS, the fully adjusted rates represented substantial reductions (more than $4 billion over five years), with fees for many items reduced by 50 percent – 80 percent, compared with 2015 rates.

Section 16007 of the Cures Act requires the Secretary to extend this transition period retroactively from June 30, 2016 to December 31, 2016, with full implementation of adjusted rates applying to items and services furnished with dates of service on or after January 1, 2017. Section 16005 likewise delays until July 1, 2017 the Secretary's authority to use CBP pricing to adjust the DMEPOS schedule for wheelchair accessories and seat and back cushions furnished in connection with Group 3 complex rehabilitative power wheelchairs.

The Cures Act also directs the Secretary to study the impact of the payment adjustment policy on the number of DME suppliers that ceased conducting business as Medicare suppliers and the availability of DME for Medicare beneficiaries in 2016.

Section 16008 requires the Secretary to consider additional information before adjusting DMEPOS fee schedule amounts based on competitive bidding pricing, effective for items and services furnished on or after January 1, 2019. First, in making any such adjustments, the Secretary must solicit and consider stakeholder input. Second, the Secretary must take into account:

- The highest bid by a winning supplier in a competitive bidding area (CBA), and
- A comparison of average travel distances and costs, average volume of items and services furnished, and the number of suppliers in CBAs and non-CBAs.

Rural Community Hospital Demonstration Program (Section 15003)

The Cures Act extends the Rural Community Hospital Demonstration for an additional five years, through the end of 2021, and expands eligibility for participation.

Improvements to the Local Coverage Determination (LCD) Process (Section 4009)

The Cures Act attempts to increase transparency around the LCD process by requiring Medicare administrative contractors to post information about the LCD on their websites at least 45 days before the effective date of such a determination.

The information should include (1) the determination in its entirety, (2) when and where the proposed LCD was first made public, (3) hyperlinks to the proposed LCD and a response to public comments, (4) a summary of evidence that was considered in the development of the LCD, and (5) an explanation of the rationale that supports the determination.

Medicare Pharmaceutical and Technology Ombudsman (Section 4010)

The Cures Act creates a new Medical Pharmaceutical and Technology Ombudsman within CMS to receive and respond to complaints, grievances and requests from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered under the Social Security Act, or for which coverage is being sought. The Ombudsman is directed to consider such complaints and requests with respect to coverage, coding, or payment for such products.

Medicare Site-of-Service Price Transparency (Section 4011)

The Cures Act seeks to facilitate price transparency with respect to the difference between hospital outpatient department services and ASC services, by publishing the estimated payment amount and estimated beneficiary liability for these services on a searchable website. This is designed to give seniors the ability to shop among

certain sites of services to identify the most cost-effective treatments.

Medicare Telehealth Services (Section 4012)

Under the Cures Act, the CMS Administrator must provide to the relevant Congressional committees certain data related to the expansion of telehealth services, including (1) the populations of Medicare beneficiaries whose care may be improved most by the expansion of telehealth services, (2) any activities by the Center for Medicare and Medicaid Innovation (CMMI) that examine the use of telehealth services, (3) the types of high-volume services that might be suitable to be furnished using telehealth, and (4) barriers that might prevent the expansion of telehealth services under the Medicare program.

Likewise, Medicare Payment Advisory Commission (MedPAC) must provide data on payment for telehealth services to the relevant Congressional committees. This data should identify (1) the telehealth services for which payment can currently be made under the Medicare fee-for-service (FFS) program, (2) the telehealth services for which payment can currently be made under private health insurance plans, and (3) which services currently reimbursed by private health insurance plans might be incorporated into the Medicare FFS program.

This section also expresses the "sense of Congress" that states that eligible originating sites should be expanding beyond those originating sites currently included in the Social Security Act. Furthermore, it is the sense of Congress that any expansion of telehealth services under the Medicare program should (1) recognize that telemedicine is safe, effective, quality health care; (2) meet or exceed the conditions of coverage and payment with respect to the Medicare program if the service was furnished in person; and (3) involve clinically appropriate means to furnish such services.

No Payment for Items and Services Furnished by Newly-Enrolled Providers or Suppliers within Temporary Moratorium Areas (Section 17004)

The Cures Act bars Medicare, Medicaid, or Children's Health Insurance Program (CHIP) reimbursement for items and services provided on or after October 1, 2017 that fall within a geographic region and provider category covered by a temporary enrollment moratorium, when the provider enrolls on or after imposition of such temporary moratorium. In addition, the Cures Act prevents beneficiaries from being charged for these items or services. State Medicaid programs may continue to make exceptions to the temporary enrollment moratoria if they determine that Medicaid beneficiary access would be adversely impacted.

Medicare Advantage Provisions (Sections 17001, 17005 and 17006)

The Cures Act delays through the end of plan year 2018 CMS's authority to terminate MA plan contracts because of unsatisfactory performance under the five-star rating system. That is, during this period, plans may not be terminated *solely* for failing to achieve minimum quality ratings under the five-star rating system, although they may still be terminated under other performance categories considered in past cycle performance reviews. Congress intends for the additional time to be used to examine the effects of socioeconomic status and dual-eligible populations on the MA star rating system.

In addition, the Cures Act establishes a continuous MA open enrollment and disenrollment period for the first three months of each year beginning in 2019. During these periods, MA-eligible and enrolled individuals will be allowed to make a one-time change to a previous election to receive benefits through the original Medicare FFS program or an MA plan, and to elect coverage under Part D. Newly MA-eligible and enrolled individuals will be permitted to make changes during the first three months in which they first became eligible. With respect to Part D prescription drug plan changes, this provision applies only to individuals who were previously enrolled in an MA plan. The provision also prohibits unsolicited marketing to MA-eligible and enrolled individuals during the open enrollment and disenrollment periods.

With regard to beneficiaries with ESRD, the Cures Act allows individuals with ESRD to enroll in any MA plan beginning in the 2021 plan year. The standardized costs of kidney acquisitions are excluded from MA benchmark capitation rates; such payments will be reimbursed under FFS Medicare. The Cures Act further requires the Secretary to consider adding a quality measure under the five-star rating system that relates to care for MA enrollees with ESRD, with the results to be posted on the CMS website no later than April 1, 2020. The Secretary is required to report to Congress no later than December 31, 2023, on the impact of these changes on (1) Medicare FFS and MA spending, (2) the number of ESRD enrollees in the Medicare FFS and MA programs, and (3) the sufficiency of data under the Medicare FFS program on individuals with ESRD in order to determine MA payment rates for ESRD enrollees.

The Cures Act also directs the Secretary to improve risk adjustment under MA by taking into account MA enrollees' total number of diseases and conditions and making adjustments as the number increases; allowing the use of at least two years of diagnosis data; and providing separate adjustments for full-benefit and other dual eligible individuals. Further, the Secretary is directed to evaluate the impact of incorporating into the

risk adjustment model additional diagnosis codes for mental health and substance use disorders, along with an adjustment for the severity of chronic kidney disease, along with other factors that should be considered in computing payment rates. Resulting changes to risk adjustment payment amounts would have to be phased in over three years beginning with 2019, with a public comment opportunity.

Finally, various studies and reports relating to the risk adjustment system and functional status are to be conducted by the MedPAC, the Secretary, and the Government Accountability Office (GAO).

Assignment of Beneficiaries under the Medicare Shared Savings Program (Section 17007)

The Cures Act directs the Secretary to consider a Medicare FFS beneficiary's use of services provided by federally qualified health centers and rural health clinics, in addition to primary care services, when assigning beneficiaries to an accountable care organization under the Medicare Shared Savings Program, beginning January 1, 2019.

Medicare Enrollment Data Reporting (Section 17002)

The Cures Act requires the Secretary to report annually to Congress on Medicare enrollment data. Such report is to include FFS, MA, and Part D Medicare enrollment data by Congressional district and state.

Welcome to Medicare Package (Section 17003)

This provision requires the Secretary to seek input from patient advocates, issuers, employers, and other stakeholders regarding the contents of the Welcome to Medicare packet, including information relating to enrollment and coverage for Medicare-eligible individuals, within six months of enactment. In addition, within one year, the Secretary must consider the materials it receives and update the Welcome to Medicare packet with information on benefit options, including Medicare FFS, MA, and Part D benefits.

MEDICAID PROVISIONS

Medicaid Reimbursement for Durable Medical Equipment (Section 5002)

Under the Consolidated Appropriations Act of 2016 (P.L. 114-113), Medicaid DME reimbursement rates are limited to Medicare FFS rates applicable in the state, including applicable competitive bidding rates, beginning January 1, 2019. The Cures Act accelerates this provision; Medicaid DME rates will be limited to Medicare rates effective January 1, 2018. The CBO estimates that this provision will save $370 million over five years.

Increasing Oversight of Termination of Medicaid Providers (Section 5005)

The Cures Act requires states and Medicaid managed care plans to report to the HHS Secretary identifying information for providers terminated from Medicare, Medicaid, or CHIP for fraud, integrity, or quality reasons. Information about such terminations will be included in a termination notification database.

In addition, the Cures Act requires Medicaid managed care contracts to specify that any provider terminated from Medicare, Medicaid, or the CHIP program will be terminated from Medicaid managed care networks, effective no later than July 1, 2018. The Act prohibits the use of federal funds for services provided by the terminated provider, beginning July 1, 2018.

The Cures Act imposes Medicaid enrollment requirements under Medicaid FFS programs and managed care plans. Specifically, states that pay for Medical Assistance on an FFS basis must require each provider who furnishes, orders, prescribes, refers, or certifies eligibility for Medicaid services to enroll with the state agency, no later than January 1, 2017. States must require managed care plan network providers to be similarly enrolled, no later than January 1, 2018.

Furthermore, the Cures Act excludes from Medicaid any provider terminated from any state CHIP plan (or Medicare or other state Medicaid plan, as under current law) if the termination is included in the termination database.

Other Medicaid Savings

The Cures Act also:

- Requires state Medicaid programs that provide benefits on an FFS basis or through a primary care case management system to provide beneficiaries with an on-line directory of participating physicians (Section 5006).
- Allows non-elderly individuals with disabilities to establish a Medicaid supplemental needs trust without filing a petition with a court (Section 5007).
- Eliminates federal Medicaid matching funds for drugs used for cosmetic purposes or hair growth, except where medically necessary, which CBO estimates will save $19 million over five years and $48 million over 10 years (Section 5008).

PENALTIES FOR VIOLATIONS OF GRANTS, CONTRACTS, AND OTHER AGREEMENTS (Section 5003)

The Cures Act includes language that clarifies and expands the OIG's authority to impose civil monetary penalties (CMPs) in cases of fraud related to HHS grants, contracts, or other agreements "for which the Secretary provides funding." The term "other agreements" could include, for example, cooperative agreements, scholarships, fellowships, loans, subsidies, payments for a specified use, donation agreements, awards, or subawards. Specifically, under this provision, the following CMPs may be imposed on any person or entity other than a program beneficiary:

- For knowingly presenting or causing to be presented a specified claim under such grant, contract, or other agreement that the person knows or should know is false or fraudulent, CMPs of not more than $10,000 for each specified claim, in addition to an "assessment" of treble damages.
- For knowingly making, using, or causing to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document submitted to receive or retain funds provided in whole or in part under the grant, contract, or other agreement, CMPs of not more than $50,000 for each offense, in addition to an assessment of treble damages.
- For knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement, CMPs of not more than $50,000 for each false record or statement, in addition to an assessment of treble damages.
- For knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property to the Secretary with respect to such grant, contract, or other agreement, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit funds or property to the Secretary with respect to such grant, contract, or other agreement, CMPs of not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay, in addition to an assessment of treble damages.
- For failing to grant timely access, upon reasonable request to the Inspector General for the purpose of audits, investigations, evaluations, or other statutory functions involving such grants, contracts, or other agreements, CMPs of not more than $15,000 for each day in violation.

Such penalties are in addition to any other penalties that may be prescribed by law. In addition, such violations may be grounds for exclusion from federal and state health care programs. The new Cures Act provisions expand the OIG's significant arsenal of CMP authorities already existing under the Social Security Act.

HEALTH INFORMATION TECHNOLOGY AND ELECTRONIC HEALTH RECORDS

As public and private payers move from FFS payment to quality-based payment and alternative payment bundles, health information technology (HIT) including EHR and digital health tools take on increasing importance. Hospitals and physicians, however, have concerns about the administrative burdens associated with EHR and HIT regulations. Lawmakers attempted to address some of these EHR and HIT concerns in Title IV of the Cures Act.

Reducing Administrative Burdens (Section 4001)

The Cures Act requires the HHS Secretary to work with stakeholders to reduce the regulatory and administrative burdens hindering the use of EHR, and to prioritize uses for HIT. In developing the strategy to reduce these administrative burdens, the Secretary of HHS, through notice and comment, must prioritize, among other things:

- Incentives for meaningful use of EHR
- The Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program
- Health information technology certification
- Quality of patient care
- Activities related to facilitating health and clinical research, public health, aligning and simplifying quality measures, and reporting clinical data

In addition, the Cures Act:

- Provides that physicians may delegate EHR documentation requirements to a person performing a scribe function, as long as the physician signs and verifies the documentation.
- Requires the National Coordinator to encourage or recognize, through existing authorities, the voluntary certification of HIT for use in medical specialties and sites of service for which technological advancement is needed.
- Mandates that the Secretary of HHS submit a report to the HIT Advisory Committee detailing statistics for

EHR Meaningful Use Incentive programs to assist in the development of standards and practices. This report must include the number of providers that did not meet the minimum criteria to attest to Meaningful Use.

Restrictions on Information Blocking (Sections 4002 and Section 4004)

The Cures Act requires the Secretary to develop provisions to ensure that HIT developers will not engage in "information blocking," or otherwise prohibit or restrict the interoperability of HIT.

- HIT developers must (1) publish application programming interfaces and allow HIT from the technology to be accessed and exchanged without special effort, and (2) successfully test the real world use of interoperability technology.
- The Secretary must convene a group of stakeholders to develop reporting criteria addressing: security, usability and user-centered design, interoperability, and conformance to certification testing. The Secretary also must award grants to support this initiative, with priority given to entities that have experience in HIT usability, interoperability, and security with respect to health care providers, hospitals, patients, and consumers.

Section 4004 of the Act defines "information blocking" as a practice that (1) is likely to interfere with, prevent, or materially discourage access, exchange or use of electronic health information, and (2) the entity knows or should know that such a practice is likely to have such an effect. It also specifies that information blocking practices may include:

- Practices that restrict authorized access, exchange or use of EHR for treatment and other permitted purposes;
- Implementing HIT in nonstandard ways that increase the complexity or burden of accessing, exchanging or using EHR; and
- Implementing HIT in a fashion that leads to fraud, waste or abuse, or impedes health information access, exchange and use.

The Act authorizes the HHS Inspector General to investigate claims that a HIT developer or other certified HIT entity has engaged in information blocking. Furthermore, the Act establishes CMPs for HIT developers up to $1 million per violation. Provider penalties will be established through rulemaking.

Interoperability – Enabling the Secure Exchange of EHR and Promotion of Standards (Section 4003)

This section provides a statutory definition of interoperability with respect to HIT that enables the secure exchange and use of electronic health information without special effort on the part of the user. The Act:

- Directs the Office of the National Coordinator (ONC) to convene stakeholders to develop a trusted exchange framework, including common agreement for exchange of information among HIT networks nationally.
- Requires the ONC to provide technical assistance to implement this exchange framework and provide for the pilot testing of the proposed framework. After implementation, the ONC must publish on its website a list of all HIT networks that have adopted this common agreement.
- Replaces the HIT Policy and Standards Committees with a new HIT Advisory Committee to address issues related to interoperability and privacy and security of health information. The Committee is charged with identifying priorities for implementation standards and certification criteria relating to the implementation of the HIT infrastructure.

Leveraging EHR to Improve Patient Care (Section 4005)

The Act requires EHR to be capable of transmitting to receiving data from registries in accordance with standards recognized by the ONC. It also requires that a HIT developer be treated as a provider for the purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of HIT.

Furthermore, the Act requires the Secretary of HHS to submit to relevant Congressional committees a report concerning the best practices and current trends to improve the integration of HIT into clinical practice.

Empowering Patients and Improving Patient Access to their EHR (Section 4006)

The Act instructs the HHS Secretary to use existing authorities to encourage partnerships between health information exchange organizations and other relevant health care entities, with the goal of offering patients access to their electronic health information in a single, user-friendly format. In addition, the Act requires the Secretary to work with the HHS Office of Civil Rights to educate health care providers on allowable uses and sharing of patient health information, and to clarify misunderstandings that currently impede lawful sharing.

Study on Interoperability and Matching Patient Data (Sections 4007 and 4008)

The Act requires the GAO to conduct two studies related to HIT:

- A study involving the methods for securely matching patient records to the correct patient, and
- A study reviewing patient access to health information, including barriers to access and methods patients may use to request their health information.

AFFORDABLE CARE ACT (ACA) SAVINGS

The Cures Act rescinds $3.5 billion from the ACA Prevention and Public Health Fund over 10 years (Section 5009). In addition, the Cures Act immediately rescinds $464 million in ACA funding for territories (Section 5011).

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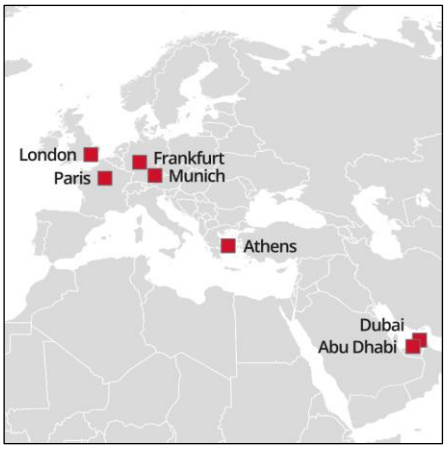

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