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Client Alert Commentary

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21st Century Cures Act Brings Medicare Reimbursement and Policy Changes in 2017

Changes include increased transparency, delayed DMEPOS payment reductions, changed reimbursement for infusion drugs, changed hospital policies and more.

On December 13, 2016, President Obama signed into law the 21st Century Cures Act (the Act) with strong bipartisan support. The Act includes several Medicare reforms and updates to existing Medicare policies affecting pharmaceutical and device manufacturers as well as healthcare providers and suppliers. Overall, the Act represents an effort to achieve Medicare and Medicaid program savings while improving access to new technologies and healthcare services for Medicare beneficiaries and Medicaid recipients. This article provides a summary of the key provisions impacting pharmaceutical and medical device manufacturers; durable medical equipment (DME) prosthetics, orthotics and supplies (DMEPOS) suppliers; providers of infusion drugs furnished through DME; home infusion therapy services; and hospitals.

The Act focuses mainly on US Food & Drug Administration policies and processes to accelerate development and approval of medical products. Consistent with this purpose, the Act furthers Medicare's commitment to new technologies by strengthening the Local Coverage Determination (LCD) development process — which governs Medicare coverage for new products and services — and creating a new Medicare Pharmaceutical and Technology Ombudsman. In addition, the Act:

- Provides temporary relief from certain regulatory requirements and reimbursement cuts for DMEPOS suppliers and hospitals, including delaying implementation of the Competitive Bidding Program (CBP) prices to non-competitive bidding areas — a legislative fix for certain off-campus provider-based hospital outpatient departments subject to reimbursement cuts — and delaying enforcement of the direct supervision requirement for critical access and rural hospitals

- Mandates the Centers for Medicaid and Medicaid Services (CMS), when developing future payment adjustments for DMEPOS suppliers, to seek stakeholder input and recognize variability between competitive and non-competitive bidding areas when using competitive bidding process information to set reimbursement rates for non-competitive bidding areas

- Instructs CMS to apply an adjustment factor when imposing the hospital readmission penalty, to account for dual-eligible populations served by hospitals

Not all of the changes are considered positive, however. The Act changes the reimbursement methodology for infusion drugs and biologics furnished through DME, and accelerates the Medicare cap on Medicaid fee-for-service payments for DMEPOS.

Given the extent of the changes in law the Act authorizes, and the significant discretion afforded to CMS, we anticipate an extensive regulatory process will accompany some of these changes, creating opportunities for stakeholders to provide input on these new and revised Medicare policies.

New LCD Transparency Requirements and Medicare Pharmaceutical and Technology Ombudsman

MACs Must Justify Local Coverage Determinations

Starting on June 11, 2017, Medicare Administrative Contractors (MACs) will be required to, among other things, publish a summary of evidence that it considered when developing an LCD. If a national coverage determination does not exist or address coverage for a product or service, MACs may develop their own coverage policies. An LCD is a coverage determination by a MAC regarding whether a particular service or item is reasonable and necessary under Medicare within that MAC's geographical jurisdiction. Under the Act, at least 45 days before a new or revised LCD is effective, MACs are required to publish on their website: (a) the LCD; (b) links to the proposed LCD and a response to comments submitted to the MAC concerning the LCD; (c) where and when the proposed LCD was first made public; (d) a summary of the evidence that the MAC considered in developing the LCD, including a list of sources; and (e) an explanation of the rationale that supports the MAC's determinations.

These changes should dramatically improve the LCD procedural process. The increased transparency will benefit stakeholders subject to and impacted by these LCDs as they will now have consistent access to the evidence the MAC considered when developing or revising the LCD. Stakeholders can also supplement that evidence with additional studies the MAC did not consider or reference.

New Medicare Pharmaceutical and Technology Ombudsman as Liaison for Manufacturers

The Secretary of the Department of Health and Human Services (the Secretary) must create a new Pharmaceutical and Technology Ombudsman prior to December 12, 2017. The Ombudsman will respond to requests, complaints and grievances from pharmaceutical, biotechnology, medical device and diagnostic product manufacturers with respect to coverage, coding and payment. This new position may give manufacturers and other stakeholders another avenue to engage with CMS on coding, coverage and payment decisions for new technologies — a vexing process to many for years now.

Partial Relief for DMEPOS Suppliers through Delay of CBP Price Expansion

The Medicare DMEPOS Competitive Bidding Program pricing framework, first adopted nearly 10 years ago, has imposed significant pricing pressure on DMEPOS suppliers. When CMS expanded the price reductions CBP imposed, from the urban competitive bid areas to the nationwide DMEPOS fee schedule, some stakeholders argued the price cuts may affect Medicare beneficiaries' access to DMEPOS in certain areas. To allow for a longer transition period to these new prices, the Act delays implementing the DMEPOS CBP ceiling payments until December 31, 2016. However, the Act also accelerates the adoption of a policy to limit Medicaid Fee for Service DMEPOS payments to Medicare rates. The Act mandates a study to evaluate how the CBP has affected patient access, and requires the Secretary to incorporate certain metrics in setting 2019 reimbursement rates using CBP information. While short-term delay and reevaluation of the DMEPOS competitive bid pricing framework may temper the immediate effects of the reduced DMEPOS rates, reduced rates based on competitive bid pricing are still on the horizon.

CBP Ceiling Payments Delayed for Six Months

Recognizing that applying the competitive bidding rates to non-competitive bidding areas, including rural areas, may affect patient access, the Act delayed implementing two policies under the DMEPOS CBP. First, the Act delays applying CBP ceiling payments to items in areas not subject to CBP, for six months. Under the Act, CMS will base payment on 50% of the CBP single payment amount (SPA) and 50% of the fees schedule amount for items furnished between January 1, 2016, and December 31, 2016 (instead of June 30, 2016). Payment will be at 100% of SPA for items and services provided on or after January 1, 2017. Second, the Act delays applying the DME CBP ceiling payment rates for accessories furnished in connection with complex rehabilitative technology (CRT) wheelchairs for six months until July 1, 2017 (instead of January 1, 2017).

Medicare Reimbursement Cap on Medicaid Reimbursement Accelerated

The Act accelerates the planned implementation of the Medicaid reimbursement limitation for DMEPOS to January 1, 2018 (rather than January 1, 2019), reducing the time for DMEPOS suppliers to adjust to this change. This provision will cap Medicaid reimbursement for DMEPOS paid under a Medicaid Fee Schedule at Medicare payment amounts, which will likely reduce reimbursement for DMEPOS.

Study to Evaluate Impact of Payment Reductions on Patient Access

A “one-size-fits-all” approach to DMEPOS pricing may have forced some DMEPOS suppliers out of business, decreasing beneficiary choice and access. The Act requires the Secretary to study by January 12, 2017, the effect of applicable payment adjustments on the number of DMEPOS suppliers that ceased to conduct business in 2016, and the availability of DMEPOS to Medicare beneficiaries in 2016.

Medicare Required to Solicit Stakeholder Feedback and Consider Certain Metrics When Setting 2019 Reimbursement Rates Using CBP Prices and Information

When establishing payment adjustments using CBP prices and information for items and services furnished on or after January 1, 2019, the Act requires the Secretary to solicit and consider stakeholder input, which allows DMEPOS suppliers who are not part of the CBP to advocate for policies that reflect the costs they incur to serve Medicare beneficiaries, and requires the Secretary to consider several metrics. First, the Secretary must consider the highest amount bid by a winning DMEPOS supplier in a competitive acquisition area (instead of median bid submitted for an item in a competitive bidding area that is currently used), which should improve reimbursement rates. Second, the Secretary must take into account a comparison of average travel distance and cost, average DME volume, and number of DMEPOS suppliers in the competitive and non-competitive acquisition areas. Evaluating these factors is critical for DMEPOS suppliers operating in non-competitive acquisition areas that do not have the benefit of supplying an exclusive territory, which previously permitted successful bidders in competitive acquisition areas to operate on thinner margins.

Reimbursement for Infusion Drugs and Home Infusion Therapy Services — a Mixed Bag

Reduced Payments for Infusion Drugs or Biologics Furnished through DME

Infused drugs and those administered intravenously, intramuscularly or subcutaneously, are typically paid under the Medicare Part B fee schedule. Effective January 1, 2017, the payment amount for infusion drugs and biologics furnished through DME will be the Average Sales Price (ASP) plus 6%, rather than the historical payment amount based on 95% of the manufacturers’ Average Wholesale Price (AWP). This change follows reports from the US Department of Health and Human Services Office of Inspector General that found that the current AWP methodology may result in excessive reimbursement for certain

drugs while underpaying for other drugs. DME-infused drugs and biologics will not be subject to the DME CBP. Providers of Part B drugs infused through DME, as well as manufacturers of such drugs, should evaluate the effect the new policy may have on reimbursement rates.

New Payment for Home Infusion Therapy Services

Most significantly, the Act creates a new payment system for certain home infusion therapy services paid under Medicare Part B. Effective in 2021, Medicare will make a single payment for the following services associated with providing in a Medicare beneficiary's home certain home infusion drugs provided by a qualified home infusion therapy supplier: (a) professional and nursing services; (b) training and education (not otherwise paid for as DMEPOS); (c) remote monitoring; and (d) monitoring services for providing home infusion therapy and drugs. Home infusion therapy suppliers (*i.e.,* a pharmacy, physician or other licensed provider or supplier) will need to be accredited by an accreditation organization designated by the Secretary, as well as satisfy certain other criteria the Secretary will develop, which will take into account standards of care established by Medicare Advantage plans for home infusion therapy.

Under the new system, a single payment will be made for each infusion drug administration calendar day in the individual's home, but such payment cannot exceed payment for infusion therapy services furnished in a physician office setting. The Secretary can establish single payment amounts for types of infusion therapy, taking into account variation in utilization of nursing services by therapy type, and the Act authorizes Medicare to use prior authorization to monitor utilization of these services. Home infusion providers should consider taking an active role as CMS develops these new payment policies.

Positive Changes for Hospitals

While the Act authorizes implementing a crosswalk for outpatient and inpatient surgical codes, which may be used to lower reimbursement in the future, the Act enacted a number of changes that will benefit hospitals. These include applying an adjustment factor to the hospital readmission penalties for hospitals with a higher proportion of dual-eligible beneficiaries; exempting mid-build off-campus provider-based hospital outpatient departments from the site neutral policy in 2018; and delaying implementation of the direct supervision requirement for critical access hospitals.

Crosswalk Codes for Inpatient and Outpatient Procedures

The Act seeks to harmonize reimbursement for hospital procedures, particularly surgical procedures, regardless of whether services are inpatient or outpatient. By January 1, 2018, the Act requires the Secretary to develop Healthcare Common Procedure Coding System (HCPCS) versions of at least 10 surgical Medicare Severity-Diagnosis Related Groups (MS-DRGs), such that surgical procedures are translated from inpatient to outpatient hospital codes. In developing the HCPCS MS-DRG definitions, the Act directs the Secretary to consult with the Medicare Payment Advisory Commission (MedPAC) and consider the analysis MedPAC conducted in translating outpatient surgical claims into inpatient surgical MS-DRGs in 2015. This crosswalk likely will be used to harmonize payments for procedures and services across inpatient and outpatient hospital departments.

Adjustment Factor for Hospital Dual-Eligible Beneficiary Populations

Hospitals are subject to payment cuts up to 3% if they have excessive readmissions within 30 days of the initial admission for certain conditions, which arguably poses an undue burden on hospitals located in underserved areas where patients may not be able to afford medications or receive services that help prevent the readmissions. The Act allows for an adjustment factor that would reduce the penalties imposed on hospitals, based on the portion of dual-eligible beneficiaries the hospitals serve, effective in 2019. Dual-eligible refers to patients who qualify for Medicare and Medicaid benefits, typically individuals

over 65 years old with limited income. The Secretary is explicitly prohibited from imposing any additional reporting requirements on hospitals in order to develop this adjustment factor. The Act also directs MedPAC to review overall hospital readmissions and whether those readmissions are related to any changes in outpatient and emergency services furnished by the hospitals. MedPAC's report to Congress is due in June 2018.

Certain "Mid-Build" Off-Campus Provider-Based Departments Exempt from Payment Reduction in 2018

The Bipartisan Budget Act of 2015 (BBA) mandated that certain off-campus provider-based departments (PBDs) receive reimbursement based on the Medicare Physician Fee Schedule, rather than the Hospital Outpatient Prospective Payment System (HOPPS), if the department had not previously received payment under the HOPPS by November 2, 2015. Because the BBA did not provide any exception for PBDs that were under construction as of the BBA enactment date, CMS applied this mandate to all off-campus PBDs that were not operating prior to November 2, 2015, including those that were under construction.[1] In response to stakeholder input, starting in 2018, the Act allows PBDs that were mid-build at the enactment of the BBA to bill under HOPPS under certain circumstances.

To be eligible for the exception, as of November 2, 2015, the hospital must have had a binding written agreement with an outside unrelated party for the construction of the off-campus PBD, and must file certain documents with CMS to demonstrate the hospital's "mid-build" status. Hospitals should expect to be audited for compliance with these requirements, as the Act directs the Secretary to conduct audits prior to December 31, 2018.

Outpatient departments of cancer hospitals that are exempt from the HOPPS are not subject to the payment reduction; however, these hospitals must also file attestations that they qualify as provider-based departments, by February 11, 2017.

Delayed Enforcement of Direct Supervision Requirement for Critical Access Hospitals and Small Rural Hospitals

In a continuation of a long-running extension, the Act delays enforcement of the direct supervision requirement for outpatient therapy services furnished in Critical Access Hospitals and Small Rural Hospitals, through 2016. The direct supervision requirement has been continuously delayed since 2010. The direct supervision standard would require that a physician or non-physician practitioner be immediately available to provide assistance and direction throughout the performance of a procedure, which can be difficult for rural hospitals to satisfy for all therapy services.

Within one year of the Act's enactment, MedPAC must submit a report to Congress analyzing the effect on beneficiaries' access to healthcare, hospital staffing needs, and healthcare quality and costs, of continuing to delay the direct supervision requirement. Congress will likely use this report to help determine whether to continue delaying enforcement of this standard.

Stakeholders Must Continue to Play an Active Role in the Act's Implementation

The 21st Century Cures Act brings a host of changes for stakeholders across the healthcare sector. Some are positive, such as increased transparency in the LCD process, the delay in implementing the direct supervision requirement for critical access hospitals, and the new exception for PBDs that were mid-build as of the BBA's enactment. Other changes may present challenges for DMEPOS suppliers and providers of infusion therapies, such as accelerating the reduction of Medicaid reimbursement rates for DMEPOS,

and the change in payment methodology for infusion drug therapies furnished through DME to ASP plus 6%. Given the extent of the changes, and significant discretion afforded to CMS to implement the changes, we anticipate that an extensive regulatory process will present opportunities for stakeholders to offer input on these Medicare policies. As Congress and CMS strive to find the proper balance between controlling healthcare costs and ensuring patient access to new technologies and quality healthcare, stakeholders should remain active and engaged in the implementation of these policies.

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[1] Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital, Final Rule with comment period and interim final rule with comment period 81 Fed. Reg. 79562, 79708 (Nov. 14, 2016).