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Federal Authorities are Targeting Continuous Glucose Monitoring (CGM) Device Reimbursement Claims Nationwide

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The Centers for Medicare and Medicaid Services (CMS) expanded Medicare coverage for continuous glucose monitoring (CGM) devices in 2018. This led to a substantial increase in Medicare reimbursement requests for these devices—which in turn led to enhanced scrutiny of the health care providers, pharmacies, and other entities submitting these reimbursement claims. One particular area of concern which is proving problematic for many Medicare participants in 2021 is the classification of CGM devices as durable medical equipment (DME).

> *"There are several potential stumbling blocks for Medicare participants when it comes to billing for CGM—including issues with regard to the classification of CGM as DME. CGM billing compliance is currently a nationwide enforcement priority, and entities that fail to establish and maintain compliance can face substantial liability in the event of an audit or investigation." – Dr. Nick Oberheiden, Founding Attorney of Oberheiden P.C.*

The Long and Winding Road to Limited Medicare Approval for CGM Devices

Continuous glucose monitoring was first introduced in 1999. While the science of glucose monitoring as a means of diagnosis dates back to the mid-1800s, it took a while for medical researchers to develop a testing methodology that could use a small enough blood sample for at-home testing. The U.S. Food and Drug Administration (FDA) issued its first approval for a CGM device in 1999, and since then several manufacturers have introduced devices that can monitor patients' glucose levels without a finger prick.

However, the Centers for Medicare and Medicaid Services (CMS) remained resistant to the idea of CGM well into the 21st century. In 2017, CMS formally took the position that CGM does not qualify for Medicare coverage as a standalone means of diagnosis. In a Ruling dated January 12, 2017, it wrote, "Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors [because] such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM . . . [and therefore] are not considered to serve the medical

purpose of making diabetes treatment decisions."

CMS expanded Medicare coverage for CGM devices in 2018, allowing coverage for smartphone use with CGMs. While not an expansion of the purposes for which use of CGM devices is reimbursable under Medicare, this was a significant change nonetheless—as authorizing billing for smartphone technology opened up the market for at-home testing significantly. In fact, today CMS still analyzes the same five criteria outlined in its January 12, 2017 ruling when determining whether CGMs are eligible for Medicare reimbursement as DME. These criteria are:

- "The beneficiary has diabetes mellitus . . . ;
- "The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump;
- "The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results;
- "Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met; and,
- "Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan."

CMS's guidance goes on to make clear that, "If any of [the] coverage criteria . . . are not met, the CGM and related supply allowance will be denied as not reasonable and necessary."

What Do Providers Need to Do to Avoid Federal Scrutiny for Medicare Fraud Related to CGM Devices?

Given that federal authorities are specifically targeting health care providers, pharmacies, and others for Medicare fraud related to CGM devices, now is the time for these individuals and entities to make sure their practices and procedures are compliant. Among other measures, this means that Medicare participants that bill for CGM devices should:

Make Sure They Know Which CGM Devices are Medicare-Compliant

Not all CGM devices are Medicare-compliant, and FDA approval does not equate to Medicare compliance. Prior to billing Medicare for a CGM device, it is imperative to ensure that the device is eligible for reimbursement. Providers and pharmacies should not rely on manufacturers' representations, but instead make their own independent determinations based upon the information that is available directly from CMS.

Exercise Caution With Regard to DME Classification for CGM Devices

Under the current Medicare billing guidelines, a device only qualifies as reimbursable DME if it is designed to last and work as intended for a minimum of three years. Many CGM devices *do not* satisfy this definition. While failure to qualify as DME does not necessarily mean that a CGM device is

ineligible for reimbursement, it *does* mean that Medicare participants need to be extremely careful to bill for these devices currently. This is a particular focus for CMS auditors, the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG), and the U.S. Department of Justice (DOJ), so errors here are particularly likely to lead to federal scrutiny.

Review Their Guidelines for CGM Billing

Given the risks of improperly billing for CGM as DME and committing other Medicare billing violations related to continuous glucose monitoring devices, providers, pharmacies, and others should carefully review their guidelines for CGM billing to ensure that they are compliant. Inadvertence is not a defense in Medicare fraud investigations, and CMS, the HHS OIG, and the DOJ all expect Medicare participants to do what is necessary to meet their compliance obligations proactively and on an ongoing basis.

Review Their Financial Relationships with Other Entities

Providers' and pharmacies' relationships with DME suppliers can also lead to trouble in the event of a Medicare fraud investigation. Improper referral and marketing relationships are ripe for federal prosecution, and unlawful rebates and "kickbacks" can lead to civil or criminal penalties for parties on both sides of the transaction. Many seemingly innocuous financial relationships that would be permissible under normal commercial circumstances are prohibited under the Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act (EKRA), so Medicare participants need to address these concerns with their unique statutory obligations in mind.

Audit Their CGM Device Billing Histories Under Medicare

Medicare participants have an obligation to proactively address any past billing mistakes. If uncovered during an audit or investigation, previously-unidentified mistakes can lead to not only recoupment liability, but also liability for fines, treble damages, and other penalties under the False Claims Act. With this in mind, entities that have concerns about their CGM device billing histories should conduct thorough audits with the oversight of their legal counsel; and, if the audit uncovers any Medicare billing violations, they must address these issues with their legal counsel's guidance as well.

Monitor for Updates to CMS's Guidelines for CGM Device Eligibility

Since CGM is still a relatively new technology within the Medicare context, providers, pharmacies, and others must monitor for updates to CMS's guidelines. In the event that CMS changes the billing codes or eligibility of CGM devices (including, but not limited to, those qualifying as DME), all entities that bill Medicare for these devices must ensure that they promptly adhere to the updated guidance.

What Should Providers Do When Contacted by CMS (or Another Federal Authority) Regarding Their CGM Device Billing History?

With CMS, the HHS OIG, and the DOJ all prioritizing enforcement with regard to Medicare billing for CGM devices, entities that bill Medicare for CGMs need to be prepared for the possibility of an audit or investigation. If contacted by auditors or federal agents, providers, pharmacies, and others should be prepared to:

Identify Relevant Documentation and Initiate an Internal Compliance Audit

Immediately upon learning of an audit or investigation, it is imperative to identify and preserve all relevant documentation. This includes Medicare compliance policies and procedures, patient records, and billing records pertaining to DME and non-DME continuous glucose monitoring devices. An internal compliance audit needs to be conducted at this time as well, as it will be necessary to determine whether (and to what extent) auditors or investigators are going to uncover Medicare billing violations.

Establish Clear Lines of Communication and a Chain of Command

All internal personnel should be instructed not to communicate with auditors or agents directly. There should be a clear chain of command, and all communications with federal authorities should be routed through the practice's or company's defense counsel.

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