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Medicare Improperly Paid Suppliers for Intermittent Urinary Catheters

REPORT HIGHLIGHTS

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Why OIG Did This Audit

- From 2014 through 2021, CMS identified high improper payments for urological supplies, which include intermittent urinary catheters (catheters).
- Because of the ongoing risk of improper payments, we conducted this nationwide audit to determine whether Medicare paid suppliers for catheters in accordance with Medicare requirements for catheters provided to enrollees from July 2021 through June 2022 (audit period).

What OIG Found

Medicare did not make some payments to suppliers for catheters in accordance with Medicare requirements:

- Payments for 88 of 105 sample items met requirements. (We did not review 2 of 105 sample items and treated them as non-errors because after we had selected our sample, we determined that Medicare contractors had denied the claims.)
- Payments for the remaining 15 sample items did not meet requirements. Specifically, medical records did not support Medicare enrollees' eligibility for curved-tip catheters or sterile catheter kits (kits), or suppliers did not meet Medicare requirements for catheter refills, proof of delivery, or a standard written order.

On the basis of our sample results, we estimated that of the $303.3 million Medicare paid for catheters and kits for our audit period, approximately $35.1 million was improperly paid. In addition, we estimated that enrollees were responsible for approximately $8.8 million in associated coinsurance.

In addition, our analysis of Medicare claims submitted after our audit period showed that suppliers billed 125,426 claims for curved-tip catheters provided to female enrollees in 2023, compared with 2,753 claims for our audit period. This large increase in claims billed may be an indication of improper claims. We shared our analysis, identifying suppliers with questionable billing patterns, with CMS so that it could take action as needed. In comments on our draft report, CMS informed us that it had already taken corrective action on 15 suppliers.

What OIG Recommends

We recommend that CMS instruct Medicare contractors to recover $11,399 in overpayments made to suppliers for the 15 sample items that did not meet Medicare requirements; perform additional medical reviews of claims for catheters and kits, which could have saved Medicare an estimated $35.1 million for our audit period; and provide additional education to suppliers on documenting eligibility for curved-tip catheters and kits and on documenting refills of catheters and kits. The full recommendations are in the report.

CMS concurred with all our recommendations except one recommendation shown in our draft report related to the 60-day-rule requirements for suppliers. We removed that recommendation.

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INTRODUCTION

WHY WE DID THIS AUDIT

From calendar years (CYs) 2014 through 2021, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing program reported that urological supplies, which include intermittent urinary catheters, were among the top 20 services or items with the highest improper payments for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).[1] In addition, durable medical equipment Medicare Administrative Contractors (DME MACs) have identified high improper payment rates for urological supplies and found that DMEPOS suppliers (suppliers) did not comply with Medicare requirements when billing for intermittent urinary catheters (e.g., the medical records that suppliers provided did not document that enrollees met eligibility requirements to receive the catheters provided).[2] Because of the ongoing risk of improper payments, we conducted this nationwide audit to determine whether the issues that CMS and DME MACs identified continued to exist for intermittent urinary catheters provided from July 1, 2021, through June 30, 2022 (audit period) to people enrolled in Medicare (enrollees).[3]

OBJECTIVE

Our objective was to determine whether Medicare paid suppliers for intermittent urinary catheters in accordance with Medicare requirements.

BACKGROUND

Medicare Program and Role of Medicare Administrative Contractors

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. CMS administers the program. Medicare Part B provides supplementary medical insurance for medical and other health services, including DMEPOS.

[1] A urinary catheter is a hollow, flexible tube that drains or collects urine from the bladder for a person who has difficulty passing urine naturally. There are several categories of urinary catheters, including intermittent catheters, which are inserted as needed to drain the bladder and then removed.

[2] In addition to the CMS and DME MAC reviews, an Office of Inspector General (OIG) evaluation found large differences between Medicare payments and suppliers' acquisition costs for intermittent urinary catheters in fiscal year 2020. OIG, *Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year* (OEI-04-20-00620), Aug. 31, 2022.

[3] This audit period correlated with the most recent claim data available at the start of our audit.

CMS contracted with two DME MACs to process and pay Medicare Part B DMEPOS claims for four DME MAC jurisdictions (A, B, C, and D), which include specific States and Territories.[4] Suppliers must submit claims to the DME MAC that serves the State or Territory in which a Medicare enrollee permanently resides.

DME MACs help CMS in its efforts to prevent and detect improper payments and promote Medicare compliance. DME MACs' responsibilities include educating suppliers on Medicare requirements and billing procedures, applying system edits to claims to determine whether claims are complete and reimbursable,[5] and performing medical reviews of claims to determine whether items provided to enrollees are medically necessary. These medical reviews may be conducted as part of CMS's Targeted Probe and Educate (TPE) program; we refer to these reviews as "TPE reviews." TPE reviews focus on specific suppliers that bill a particular item or service, typically evaluate 20 to 40 claims per supplier for an item or a service, and provide individualized education to suppliers based on the results of these reviews.[6] DME MACs analyze available data to identify items and suppliers for TPE reviews.

Medicare Coverage of Intermittent Urinary Catheters

An intermittent urinary catheter is a thin, flexible tube that is temporarily inserted into the bladder through the urethra to drain urine for people who have difficulty passing urine naturally. The external end of the tube may be left open, allowing the urine to drain into a receptacle, or can be attached to an external drainage bag, which collects the urine. After the bladder is emptied, the intermittent catheter is removed, and a new one may be inserted several times per day to empty the bladder.[7]

Intermittent urinary catheters are covered under the Medicare Part B benefit for prosthetic devices for people who have a permanent impairment of urination (i.e., permanent urinary incontinence (involuntary loss of urine) or permanent urinary retention (inability to voluntarily

[4] CGS Administrators, LLC, processes claims for DME MAC jurisdictions B and C. Noridian Healthcare Solutions, LLC, processes claims for DME MAC jurisdictions A and D.

[5] An edit is programming within the standard claims processing system that selects certain claims; evaluates or compares information on the selected claims or other accessible sources; and, depending on the evaluation, takes action on the claims, such as paying them in full, paying them in part, or suspending them for manual review.

[6] The TPE program's process typically includes up to three rounds of prepayment or postpayment probe reviews, each of which may be followed by one-on-one education for providers that are found to be noncompliant (CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.5.).

[7] There are three main categories of urinary catheters: (1) intermittent urinary catheters, which are removed after each use; (2) indwelling urinary catheters, which are inserted and left in the bladder for a period of time; and (3) external catheters, which are not inserted into the bladder.

empty the bladder or pass urine)). A treating practitioner orders catheters for an enrollee, and a supplier fulfills the order.[8]

Intermittent urinary catheters come in many sizes, materials (e.g., latex or silicone), and shapes (i.e., straight tip and curved tip). Suppliers bill Medicare for intermittent urinary catheters (catheters) using one of the following three Healthcare Common Procedure Coding System (HCPCS) codes:[9, 10]

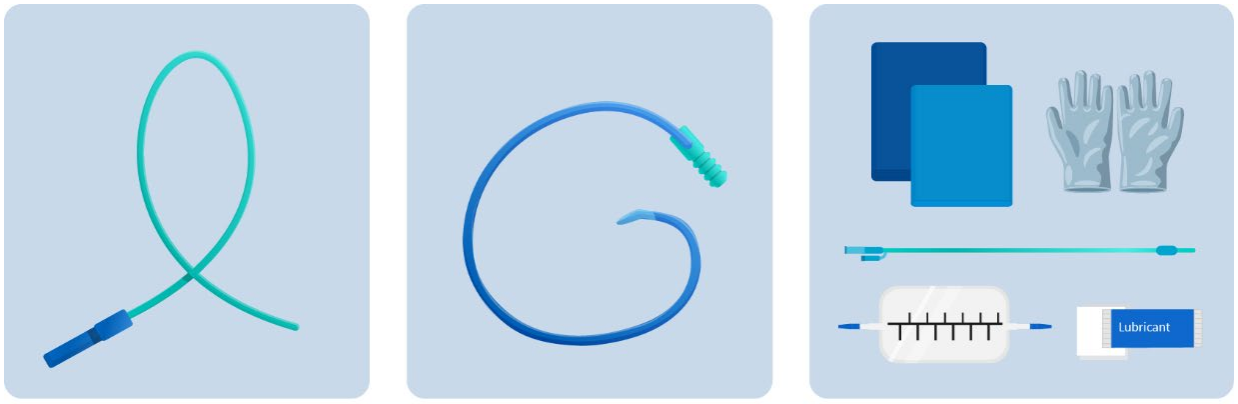
- HCPCS code A4351 is used to bill for a straight-tip catheter.

- HCPCS code A4352 is used to bill for a curved-tip catheter (also called a Coude-tip catheter). Medicare covers a curved-tip catheter if it is medically necessary (e.g., an enrollee is unable to use a straight-tip catheter).

- HCPCS code A4353 is used to bill for a sterile catheter kit, which includes a straight-tip or curved-tip catheter with all necessary insertion supplies (e.g., lubricant, gloves, an antiseptic solution, and a collection tray or bag to facilitate sterile use of the catheter).

The figure shows pictures of the two types of catheters (i.e., a straight-tip catheter and a curved-tip catheter) and a sterile catheter kit.

Figure: The Two Types of Catheters and a Sterile Catheter Kit



[8] A treating practitioner may be a physician, physician assistant, nurse practitioner, or clinical nurse specialist.

[9] Because this report covers only intermittent urinary catheters, we refer to them simply as "catheters" throughout the rest of this report.

[10] HCPCS is a standardized coding system that is used to identify products, supplies, and services for claim submission. During our audit period, the average Medicare-allowed amount for a straight-tip catheter was $2.02, for a curved-tip catheter was $7.43, and for a sterile catheter kit was $8.39. The Medicare-allowed amounts for these supplies varied based on the date of service and an enrollee's State of residence.

Medicare Payment Requirements for Intermittent Urinary Catheters

The Social Security Act (the Act) states that Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Act § 1862(a)(1)(A)). In addition, Medicare payments must not be made to a supplier for an item or a service unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (the Act § 1833(e)). Federal regulations state that the supplier must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

All DMEPOS items require a standard written order (42 CFR § 410.38(d)(1)). In addition, DME MACs' Local Coverage Determination (LCD) for urological supplies (LCD L33803) contains coverage and documentation requirements, including requirements for supporting that catheters are reasonable and necessary (i.e., requirements to support that an enrollee is eligible for catheters provided).[11] It is expected that an enrollee's medical records will reflect the need for the care or item provided. To justify payment for a DMEPOS item, such as a catheter, a supplier must provide medical record documentation upon request (LCD L33803).

HOW WE CONDUCTED THIS AUDIT

Our audit covered $303.3 million in Medicare Part B payments to 2,659 suppliers for 575,229 claim lines for intermittent urinary catheters provided to 110,847 enrollees during our audit period. (Each claim line was for a supply of catheters or sterile catheter kits provided to a single enrollee on a single date of service.) The enrollee coinsurance associated with these catheters and sterile catheter kits totaled $78.7 million.[12] We selected a stratified random sample of 105 claim lines, for which Medicare paid 39 suppliers $87,944 (with $22,044 in associated enrollee coinsurance payments).[13]

We reviewed documentation that suppliers provided us to determine whether Medicare paid for catheters and sterile catheter kits in accordance with Medicare requirements. We considered payments that did not meet requirements to be improper payments. DME MACs confirmed the findings for the sampled claim lines for which supporting documentation did not

[11] An LCD is a determination made by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service in the MAC's jurisdiction. MACs develop LCDs through an evidence-based process, with opportunities for the public to participate and comment. During our audit period, LCD L33803 ("Urological Supplies," revision effective Apr. 1, 2021) was used by both DME MACs and covered all four DME MAC jurisdictions.

[12] Medicare pays suppliers 80 percent of the allowed amount for covered DMEPOS items, and enrollees are responsible for the remaining 20 percent. However, not all enrollees pay out of pocket for coinsurance. Some enrollees have secondary insurance coverage (e.g., Medicaid) that will pay the coinsurance amount.

[13] Our sample consisted of paid claim lines for catheters billed with HCPCS codes A4351 and A4352 and sterile catheter kits billed with HCPCS code A4353. For simplicity, we refer to sampled claim lines as "sample items" in the "Findings" and "Recommendations" sections of this report.

substantiate that the claim lines were paid in accordance with Medicare requirements for curved-tip catheters or sterile catheter kits. In addition, we analyzed CY 2023 catheter claim data to identify any changes in billing trends after our audit period.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology, Appendix B describes our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDINGS

Medicare did not make some payments to suppliers for intermittent urinary catheters in accordance with Medicare requirements. Payments for 88 of the 105 sample items met Medicare requirements. However, payments to 12 suppliers for 15 sample items, totaling $11,399 (with $2,856 in associated enrollee coinsurance payments), did not meet requirements.[14] Specifically, we found the following deficiencies:[15]

- For 10 sample items, medical records did not support enrollees' eligibility for curved-tip catheters or sterile catheter kits.[16]

- For seven sample items, suppliers did not meet Medicare requirements for catheter refills, proof of delivery, or a standard written order.

On the basis of our sample results, we estimated that of the $303.3 million Medicare paid for catheters and sterile catheter kits for our audit period, approximately $35.1 million was improperly paid.[17] In addition, we estimated that enrollees were responsible for approximately

[14] We did not review 2 of 105 sample items but treated them as non-errors because after we had selected our sample, we determined that the DME MACs had denied the claims and adjusted the payment amounts for these sample items to $0.

[15] The total number of deficiencies is greater than 15 because 2 sample items had more than 1 deficiency.

[16] The medical records did support that most of these enrollees had a permanent impairment of urination, and these enrollees may have qualified for straight-tip catheters. Therefore, for 8 of these 10 sample items, we considered allowable the portion that would have been paid for an equivalent supply of straight-tip catheters. For the remaining two sample items, we considered the entire amount unallowable because these sample items had other deficiencies.

[17] The estimated improper Medicare payment amount was $35,079,833.

$8.8 million in associated coinsurance.[18] The improper payments occurred mainly because suppliers did not fully understand Medicare coverage requirements, as well as the requirements for documenting eligibility for curved-tip catheters and sterile catheter kits and for documenting refills of catheters. In addition, DME MACs' medical reviews (e.g., TPE reviews) and education of suppliers may not have been sufficient to prevent improper payments.

MEDICAL RECORDS DID NOT SUPPORT ENROLLEES' ELIGIBILITY FOR INTERMITTENT URINARY CURVED-TIP CATHETERS OR STERILE CATHETER KITS

Medicare Requirements

For a supplier to receive Medicare payment, there must be documentation in an enrollee's medical record of the medical necessity for a curved-tip catheter (LCD L33803). An example in the LCD is the inability to use a straight-tip catheter.

Medicare covers a sterile catheter kit if an enrollee: (1) resides in a nursing facility; (2) is immunosuppressed (e.g., on cancer chemotherapy or has AIDS); (3) has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization;[19] (4) is pregnant and has a spinal cord injury and neurogenic bladder;[20] or (5) has had distinct, recurrent urinary tract infections (e.g., with a urine culture showing greater than 10,000 colony-forming units of a urinary pathogen), while on a program of sterile intermittent catherization (i.e., a straight-tip or curved-tip catheter together with sterile lubricant), twice within the 12-month period before initiation of a sterile catheter kit (LCD L33803).[21]

Suppliers Provided Medical Records That Did Not Support Enrollees' Eligibility for Curved-Tip Catheters or Sterile Catheter Kits

For 10 sample items, suppliers provided medical records that did not support enrollees' eligibility for curved-tip catheters or sterile catheter kits. Specifically:

- For six sample items, medical records did not document medical necessity for use of curved-tip catheters. For example, a supplier billed for 450 curved-tip catheters, for which Medicare paid $2,290 (with $572 in associated enrollee coinsurance). The

[18] The estimated enrollee coinsurance amount was $8,790,209.

[19] Vesico-ureteral reflux is a condition in which urine flows backward from the bladder to the ureters and kidneys. (Ureters are the ducts by which urine passes from the kidneys to the bladder.)

[20] Neurogenic bladder is a urinary tract dysfunction in which the bladder does not empty properly because of a neurological condition or spinal cord injury.

[21] To be considered to have a urinary tract infection, an enrollee must also have a concurrent condition, such as a fever, change in urinary urgency, or increased muscle spasms.

supplier provided the enrollee's medical record, which stated that the enrollee needed a curved-tip catheter. However, the medical record did not document the medical necessity for use of a curved-tip catheter (i.e., did not specify why the enrollee needed a curved-tip catheter or could not use a straight-tip catheter), as required by LCD L33803. The medical record did support that the enrollee had a permanent impairment of urination and may have qualified for straight-tip catheters, for which Medicare would have paid $713 (with $178 in associated enrollee coinsurance). Therefore, Medicare improperly paid $1,577 (with $394 in associated enrollee coinsurance) for these catheters.

- For four sample items, medical records did not document that an enrollee had a condition that required use of a sterile catheter kit. For example, a supplier billed for 200 sterile catheter kits, for which Medicare paid $1,304 (with $326 in associated enrollee coinsurance). The supplier provided the enrollee's medical record, which included only one urine culture test result showing a urinary tract infection. The medical record did not support that the enrollee had two urine cultures of greater than 10,000 colony-forming units of a urinary pathogen within a 12-month period before initiation of a sterile catheter kit, or any of the other conditions for coverage as required by LCD L33803. The medical record did support that the enrollee had a permanent impairment of urination and may have qualified for straight-tip catheters, for which Medicare would have paid $286 (with $72 in associated enrollee coinsurance). Therefore, Medicare improperly paid $1,018 (with $254 in associated enrollee coinsurance) for these catheters.

SUPPLIERS DID NOT MEET MEDICARE REQUIREMENTS FOR REFILLS, PROOF OF DELIVERY, OR A STANDARD WRITTEN ORDER

Medicare Requirements

For all DMEPOS items provided on a recurring basis, a supplier is required to have contact with the enrollee or caregiver (or designee) before dispensing a new supply of items to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. A supplier must not deliver a refill without a refill request from the enrollee. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days before the end of usage for the current product (LCD L33803).

A supplier must maintain proof of delivery in its files (42 CFR § 424.57(c)(12)).[22] All services or items that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary (LCD L33803).

[22] Suppliers must maintain documentation for 7 years from the date of service (42 CFR § 424.516(f)(1)(A)).

As a condition for Medicare payment, the standard written order or prescription for a DMEPOS item must include the following elements: (1) the enrollee's name or Medicare Beneficiary Identifier, (2) a general description of the item, (3) the quantity to be dispensed, (4) the order date, (5) the treating practitioner's name or National Provider Identifier (NPI), and (6) the treating practitioner's signature (42 CFR § 410.38(d)(1)(i)).[23] In addition, the written order must be communicated to the supplier before claim submission (42 CFR § 410.38(d)(1)(ii)(B)). If the supplier bills for an item without first receiving a completed standard written order, the claim shall be denied as not reasonable and necessary (LCD L33803).

Suppliers' Records Did Not Support That Requirements for Refills, Proof of Delivery, or a Standard Written Order Were Met

For seven sample items, suppliers did not meet Medicare requirements for refills, proof of delivery, or a standard written order. Specifically:

- For five sample items, suppliers did not provide records of refills (i.e., refill requests) of catheters or a sterile catheter kit, or suppliers delivered the refills sooner than 10 days before the end of the usage of the existing supplies. For example, a supplier billed for 200 sterile catheter kits, for which Medicare paid $1,185 (with $296 in associated enrollee coinsurance), but supporting documentation did not include a refill record showing that the supplier contacted the enrollee before dispensing a refill of sterile catheter kits.

- For 1 sample item, a supplier billed for 60 straight-tip catheters, for which Medicare paid $66 (with $17 in associated enrollee coinsurance). However, the supplier did not provide proof-of-delivery documentation to support that the catheters were delivered to the enrollee.

The Importance of Having an Adequate Refill Record

A refill record must document that a supplier contacted an enrollee before dispensing a refill of supplies. If the supplier does not contact the enrollee to confirm whether any changes were made to the standard written order, the supplier may dispense refill supplies that are not appropriate for the enrollee's current use of the supplies, which may impact the enrollee's well-being. For example, an enrollee's medical condition may have changed to require the use of a sterile catheter kit to prevent urinary tract infections, and the enrollee's health may be seriously impacted if the supplier continues to provide catheters without insertion supplies. In addition, failing to contact the enrollee before dispensing a refill of supplies could result in wasteful spending if the enrollee still has a significant supply on hand and is provided supplies that are not needed.

[23] The NPI is a unique 10-digit identification number that CMS assigns to a provider.

- For 1 sample item, a supplier billed for 30 straight-tip catheters, for which Medicare paid $51 (with $13 in associated enrollee coinsurance). However, the standard written order was inadequate because it did not specifically identify the treating practitioner.

SUPPLIERS DID NOT FULLY UNDERSTAND MEDICARE COVERAGE AND DOCUMENTATION REQUIREMENTS

The improper payments occurred mainly because suppliers did not fully understand Medicare coverage requirements, as well as the requirements for documenting eligibility for curved-tip catheters and sterile catheter kits and for documenting refills of catheters and sterile catheter kits. We contacted 12 suppliers associated with 15 sample items that did not comply with Medicare requirements, which had 17 deficiencies, to obtain an understanding of why these deficiencies occurred. Based on the suppliers' responses, we determined that the suppliers did not fully understand Medicare requirements.

Of the 17 deficiencies, 3 deficiencies occurred because suppliers did not fully understand the coverage requirements and how to determine whether eligibility for curved-tip catheters was properly documented in the medical records. Suppliers' responses indicated that they believed that the enrollees' medical conditions or diagnoses listed in the medical records were sufficient to support the medical necessity of curved-tip catheters. For example, for one sample item, to support an enrollee's eligibility for curved-tip catheters, a supplier referred to a note in the medical record that stated: "Patient needs a coude [i.e., curved-tip] catheter due to BPH [benign prostatic hyperplasia]."[24] However, the medical record did not document that a curved-tip catheter was necessary for this enrollee. DME MACs informed us that a diagnosis alone (e.g., for BPH) would not indicate that the requirement for a curved-tip catheter was met. Furthermore, some enrollees in our sample who were prescribed straight-tip catheters also had BPH.

In addition, three deficiencies occurred because suppliers did not fully understand the coverage requirements and how to determine whether eligibility for sterile catheter kits was properly documented in the medical records. The suppliers submitted claims for sterile catheter kits when the medical records noted only that enrollees had urinary tract infections and did not include any urine-culture test results or included only one instance of a urine culture with greater than 10,000 colony-forming units of a urinary pathogen.[25] Suppliers' responses implied that they: (1) believed notations in the medical records indicating that an enrollee had urinary tract infections were sufficient to support the enrollee's eligibility for sterile catheter kits and (2) were not aware that a medical record must support two confirmed urinary tract infections with urine cultures of greater than 10,000 colony-forming units within the 12-month period before initiation of a sterile catheter kit, as required by LCD L33803.

[24] BPH is a noncancerous enlargement of the prostate gland.

[25] The medical records did not support that the enrollees met any of the other eligibility conditions that required use of a sterile catheter kit.

Furthermore, three deficiencies occurred because suppliers did not fully understand the requirements for providing and documenting refills of catheters and sterile catheter kits. When we followed up with suppliers regarding missing documentation for these refills, suppliers either provided the same documentation they had originally provided, which did not include support that the supplier had contacted the enrollee before delivering the refills, or referred us to other documents, such as the standard written order, that did not support that Medicare requirements had been met. For example, instead of providing the requested refill document for a sample item, a supplier referred to a "statement of medical necessity" document (i.e., a standard written order). However, the document did not show that the supplier contacted the enrollee before dispensing a refill of catheters. Suppliers' responses implied that suppliers were not aware that they were required to contact an enrollee before delivering a refill of catheters or sterile catheter kits.

Finally, three deficiencies occurred because suppliers made administrative errors. For example, one supplier stated that it was unable to provide proof-of-delivery documentation from the U.S. Postal Service to support that supplies were delivered to an enrollee.[26]

DME MACs' MEDICAL REVIEWS AND EDUCATION OF SUPPLIERS MAY NOT HAVE BEEN SUFFICIENT TO PREVENT IMPROPER PAYMENTS

During our audit period, DME MACs conducted medical reviews of some claims for catheters and sterile catheter kits (e.g., TPE reviews) and provided some educational opportunities (e.g., webinars) to suppliers on Medicare requirements for catheter claims. However, our findings indicate that additional medical reviews and educational efforts may help improve supplier compliance with Medicare requirements. For example, to help prevent improper payments, DME MACs could provide additional webinars with more emphasis on proper documentation of enrollee eligibility and of refills for catheters and sterile catheter kits. Furthermore, because the deficiencies we identified can be detected only by reviewing supporting documentation, additional medical reviews (e.g., prepayment or postpayment reviews) of catheter claims submitted by suppliers could have helped DME MACs to detect improper payments and identify high-risk suppliers that frequently submit claims that do not meet Medicare requirements. Additionally, by performing more TPE reviews during our audit period, DME MACs could have helped ensure that suppliers were aware of Medicare requirements and available educational resources for catheter claims.[27]

[26] For five deficiencies, suppliers did not provide the reasons those deficiencies occurred.

[27] Generally, prepayment and postpayment reviews target specific HCPCS codes, not specific suppliers. On the other hand, TPE reviews target specific suppliers and consist of up to three rounds of reviews of a supplier. In each round, the DME MAC reviews from 20 to 40 claims and provides one-on-one education to the supplier at the conclusion of the round.

MEDICARE IMPROPERLY PAID SUPPLIERS AN ESTIMATED $35.1 MILLION FOR INTERMITTENT URINARY CATHETERS, AND ENROLLEES WERE RESPONSIBLE FOR AN ESTIMATED $8.8 MILLION IN COINSURANCE

Medicare paid 12 suppliers $11,399 for 15 sample items that did not meet Medicare requirements (with $2,856 in associated coinsurance payments). On the basis of our sample results, we estimated that of the $303.3 million paid for catheters and sterile catheter kits for our audit period, approximately $35.1 million was improperly paid. In addition, we estimated that enrollees were responsible for approximately $8.8 million in associated coinsurance.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services instruct DME MACs to do the following:

- Recover $11,399 in overpayments made to suppliers for the 15 sample items that did not meet Medicare requirements.

- Perform additional medical reviews of claims for intermittent urinary catheters and sterile catheter kits, which could have saved Medicare an estimated $35,079,833 for our audit period.

- Provide additional education to suppliers on documenting eligibility for intermittent urinary curved-tip catheters and sterile catheter kits and on documenting refills of catheters and sterile catheter kits. For example, CMS could emphasize the following:

    - Medical records that list only a diagnosis without adequate documentation of an enrollee's inability to use a straight-tip catheter are insufficient to support medical necessity for use of a curved-tip catheter.

    - Notations of urinary tract infections in medical records are insufficient to support that an enrollee is eligible for sterile catheter kits, and there must be documentation supporting that the enrollee: (1) had two instances of urine cultures with greater than 10,000 colony-forming units of a urinary pathogen during a 12-month period before initiation of a sterile catheter kit and (2) had one or more qualifying concurrent conditions.

    - There must be documentation supporting that a supplier contacted an enrollee before dispensing a refill of catheters or sterile catheter kits.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our three recommendations as shown in this final report and provided information on actions that it planned to take to

address those recommendations. However, CMS did not concur with a recommendation shown in our draft report related to the 60-day-rule requirements for suppliers.[28] CMS's comments are included in their entirety as Appendix D.

Regarding our first recommendation, CMS stated that it will direct the DME MACs to recover the overpayments we identified consistent with relevant law and the agency's policies and procedures. Regarding our second recommendation, CMS stated that it will notify the DME MACs of our audit so that they may evaluate the risk associated with these claims as part of their annual Improper Payment Reduction Strategy. Regarding our third recommendation, CMS stated that it will direct the DME MACs to continue to provide education consistent with the payment and coverage policies.

CMS did not concur with our recommendation, as stated in our draft report, to instruct DME MACs to notify appropriate suppliers so that they could exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule.[29] CMS said that this recommendation would require the identified 12 suppliers to conduct a medical and/or documentation review of each of their associated claims. CMS stated that it does not believe that this would be an efficient use of the 60-day rule and that the return on investment would be low. CMS requested that we remove this recommendation.

After reviewing CMS's comments and CMS's pending revisions of the 60-day-rule regulations, we removed this recommendation.[30]

[28] Our draft report contained a recommendation that CMS instruct the DME MACs to, based on the results of this audit, notify appropriate suppliers so that the suppliers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

[29] Generally, under the 60-day rule, upon receiving credible information of potential overpayments, suppliers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 FR 7654 (Feb. 12, 2016).

[30] Effective Jan. 1, 2025, CMS is amending its regulations regarding the standard for an "identified overpayment" under Medicare Parts A, B, C, and D to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act, which provides that the terms "knowing" and "knowingly" have the meanings given those terms in the False Claims Act at 31 U.S.C. § 3729(b)(1)(A). See CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies Final Rule, available online at https://public-inspection.federalregister.gov/2024-25382.pdf (accessed on Nov. 19, 2024) and scheduled to be published in the Federal Register on Dec. 9, 2024. CMS stated that these revisions were made in response to *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), which was reversed in part on other grounds in *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (2022), wherein the court held that the "reasonable diligence" standard in the Medicare Part C regulation was improper.

OTHER MATTERS

Our analysis of claims for catheters and sterile catheter kits that suppliers submitted after our audit period further emphasizes the need for sufficient oversight activities for catheter claims. Our analysis showed that in CY 2023 the number of Medicare claims for catheters increased substantially. Specifically, suppliers billed 125,426 claims for curved-tip catheters provided to female enrollees in CY 2023, compared with 2,753 claims for our audit period.[31] This large increase in claims billed for curved-tip catheters may be an indication of improper claims because the use of these catheters in female enrollees is rarely reasonable and necessary (LCD L33803).[32] We shared our analysis, identifying suppliers with questionable billing patterns, with CMS to further review and so that it could take action as needed.[33]

In written comments on our draft report, CMS informed us that it had already taken corrective action to prevent more than 99 percent of payments to 15 potentially fraudulent suppliers.[34]

[31] Our draft report included Medicare claim payment amounts for curved-tip catheters provided to female enrollees in CY 2023. However, in written comments on our draft report, CMS stated that these payment amounts are misleading because claims "may appear as 'paid' regardless of whether payments are issued, if payments are held by a payment suspension pending an investigation, or if payments are applied to a pre-existing debt." Therefore, we updated this section to show the number of claims that suppliers billed for curved-tip catheters instead of claim payment amounts.

[32] Our stratified random sample did not include any claim lines for curved-tip catheters provided to female enrollees. According to one DME MAC, the majority of curved-tip catheters are used by male patients with enlarged prostates.

[33] We provided CMS with a list of all 153 suppliers that were paid for curved-tip catheters provided to female enrollees in CY 2023. Of these 153 suppliers, 4 suppliers accounted for more than 98.6 percent of the amount paid for curved-tip catheters provided to female enrollees in CY 2023. We did not audit catheter claims submitted in CY 2023 and therefore did not determine whether these claims were properly paid.

[34] CMS identified suppliers that had a suspicious increase in billings for all intermittent urinary catheters and took action on 15 suppliers. CMS did not provide details of the 15 suppliers for which they took corrective action. Some of these 15 suppliers may have been on our list of suppliers that were paid for curved-tip catheters provided to female enrollees.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $303,324,907 in Medicare Part B payments to 2,659 suppliers for 575,229 claim lines for intermittent urinary catheters provided to 110,847 enrollees from July 1, 2021, through June 30, 2022 (audit period). The enrollee coinsurance associated with these catheters and sterile catheter kits totaled $78,728,213. We selected a stratified random sample of 105 claim lines, for which Medicare paid 39 suppliers $87,944 (with $22,044 in associated enrollee coinsurance payments).

We reviewed documentation that suppliers provided us for the sampled claim lines to determine whether Medicare paid for catheters and sterile catheter kits in accordance with Medicare requirements. We considered payments that did not meet requirements to be improper payments. DME MACs confirmed the findings for the sampled claim lines for which supporting documents did not substantiate that the claim lines were paid in accordance with Medicare requirements for curved-tip catheters and sterile catheter kits. In addition, we analyzed CY 2023 claim data for catheters and sterile catheter kits to identify any changes in billing trends after our audit period.

We did not perform an overall assessment of CMS's internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective. Specifically, we interviewed CMS and contacted DME MACs officials to gain an understanding of: (1) Medicare requirements for catheters and sterile catheter kits and (2) claims processing procedures and system edits for catheter claims.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file, but we did not assess the completeness of the data. We assessed the reliability of the claims data from CMS's NCH file by: (1) considering prior data reliability assessments of NCH file data and (2) performing electronic testing on the data (e.g., checking that the audit data were within our audit scope and testing for duplicate claims). We determined that the data were sufficiently reliable for the purposes of this audit.

We conducted our audit from December 2022 through August 2024.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

- interviewed CMS officials to gain an understanding of Medicare requirements, claims processing procedures and system edits, and CMS guidance to DME MACs for catheters and sterile catheter kits;

- contacted DME MACs officials to gain an understanding of the reimbursement requirements, claims processing procedures and system edits, and education provided to suppliers on catheters and sterile catheter kits;

- obtained from CMS's NCH file the paid Medicare Part B claims for catheters;

- created a sampling frame of 575,229 Medicare Part B paid claim lines with payment amounts of $50 or more for catheters billed with HCPCS codes A4351 and A4352 and sterile catheter kits billed with HCPCS code A4353 with dates of service during our audit period, for which Medicare paid a total of $303,324,907;

- selected a stratified random sample of 105 claim lines, consisting of 35 claim lines for each of the 3 HCPCS codes (Appendix B);

- reviewed data from CMS's Common Working File for the selected claims to determine whether the claims had been canceled or adjusted;

- requested supporting documentation from the suppliers for 103 of the 105 sampled claim lines;[35]

- reviewed suppliers' supporting documentation to determine whether the sampled claim lines were paid in accordance with Medicare requirements;

- requested DME MACs' confirmation of our findings for the sampled claim lines for which the supporting documentation did not substantiate that the claim lines were paid in accordance with Medicare requirements for curved-tip catheters or sterile catheter kits;

- requested that the suppliers provide a reason for submitting claim lines that were not paid in accordance with Medicare requirements;

- estimated the amount that Medicare paid to suppliers for claim lines for catheters and sterile catheter kits that did not meet Medicare requirements and the associated enrollee coinsurance amount (Appendix C);

[35] We did not request supporting documentation for two sampled claim lines because after we had selected our sample, we determined that these claim lines were adjusted by DME MACs and reflected payment amounts of $0.

- analyzed claims for catheters and sterile catheter kits that were provided to enrollees in CY 2023 (after our audit period); and

- discussed the results of our audit with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame consisted of 575,229 Medicare Part B paid claim lines for catheters billed with HCPCS codes A4351 and A4352 and sterile catheter kits billed with HCPCS code A4353 with dates of service from July 1, 2021, through June 30, 2022, for which Medicare paid a total of $303,324,907. The sampling frame consisted of Medicare Part B claim lines with payment amounts of $50 or more and that had not been previously excluded by Recovery Audit Contractors or reviewed by DME MACs.

SAMPLE UNIT

The sample unit was a Medicare Part B paid claim line.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample containing three strata. (See Table 1.)

Table 1: Strata in Sampling Frame

Stratum	Description	Number of Frame Units	Frame Dollar Value	Sample Size
1	Claim lines with HCPCS code A4351	378,652	$112,624,203	35
2	Claim lines with HCPCS code A4352	165,612	152,544,605	35
3	Claim lines with HCPCS code A4353	30,965	38,156,099	35
Total		**575,229**	**$303,324,907**	**105**

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the Office of Inspector General (OIG), Office of Audit Services (OAS) statistical software.

METHOD OF SELECTING SAMPLE ITEMS

For each stratum, we sorted the sample units by the Integrated Data Repository link line number in ascending order. We then consecutively numbered the sample units in each stratum in the sampling frame. After generating random numbers according to our sample design, we selected the corresponding frame units for review.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate the amount that Medicare paid suppliers and the associated coinsurance amount for claim lines for catheters and sterile catheter kits that did not meet Medicare requirements. We used this software to calculate the point estimates and the corresponding lower and upper limits at the two-sided 90-percent confidence level. (See Appendix C for our estimates.)

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Details

Stratum	Frame Size	Value of Frame	Value of Coinsurance Related to Frame	Sample Size	Value of Sample	Value of Coinsurance Related to Sample
1	378,652	$112,624,203	$28,858,487	35	$9,812	$2,461
2	165,612	152,544,605	39,491,911	35	29,182	7,323
3	30,965	38,156,099	10,377,815	35	48,950	12,260
Total	**575,229**	**$303,324,907**	**$78,728,213**	**105**	**$87,944**	**$22,044**

Table 3: Sample Results

Stratum	Number of Improperly Paid Claim Lines	Value of Improperly Paid Claim Lines	Value of Coinsurance Related to Improperly Paid Claim Lines
1	2	$117	$29
2	8	6,195	1,553
3	5	5,087	1,274
Total	**15**	**$11,399**	**$2,856**

Table 4: Estimated Values of Improper Payments and Associated Coinsurance in the Sampling Frame (*Limits Calculated at the 90-Percent Confidence Level)*

	Estimated Improper Payments	Coinsurance
Point estimate	$35,079,833	$8,790,209
Lower limit	20,777,944	5,208,174
Upper limit	56,060,167	14,039,180

APPENDIX D: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 27, 2024

TO: Juliet T. Hodgkins
Principal Deputy Inspector General
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Improperly Paid Suppliers an Estimated $35 Million of the $303 Million Paid for Intermittent Urinary Catheters (A-09-22-03019)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS recognizes the importance of continuing to provide Medicare beneficiaries with access to medically necessary items and services and, at the same time, working to protect the Medicare Trust Funds from improper payments. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and post-payment reviews. As part of this strategy, CMS recovers identified overpayments in accordance with agency policies and procedures.

Furthermore, CMS is committed to preventing fraud and protecting people with Medicare from falling victim to fraud. To that end, we can take swift actions to prevent illegitimate payments from going to bad actors when we have credible allegations of fraud. CMS does not confirm or discuss the existence of any ongoing investigation to ensure we do not compromise the integrity of the investigative process. However, that does not mean that CMS is not taking actions behind the scenes.

In this report, the OIG conducted a documentation review and found that some claims for catheters were not paid in accordance with Medicare requirements. OIG attributed these improper payments to issues with medical necessity and documentation errors. As a result of these findings, OIG estimates that approximately $35.1 million, or 14.3 percent, of the $303.3 million paid for catheters from July 1, 2021 through June 30, 2022, was improperly paid to suppliers. OIG has issued recommendations to CMS based on these findings, and CMS' responses are provided below.

The OIG's report also includes an "Other Matters" section which states that Medicare payments for catheters increased substantially in calendar year 2023 and that Medicare paid $216.5 million for curved-tip catheters provided to female enrollees in calendar year 2023. CMS has expressed to OIG that these statements are misleading. As noted below, CMS has taken numerous proactive actions since CMS identified the issue in early 2023, prior to OIG sharing their findings in this report. Furthermore, CMS would like to emphasize that the OIG Office of Audit Services did not

present the calendar year 2023 data analysis to CMS when CMS and OIG discussed the results of the audit as described in the OIG's audit methodology. CMS notes that OIG did not conduct a medical or documentation review to determine any cause associated with the increase in billing. As such, the causes attributed to OIG's medical review for the original audit period, should not be attributed to the cause of the spike in billing in 2023.

It is important to note that just because a claim is marked "payable" does not mean funds will be paid – that is not the final step in the process. When a Medicare Payment Suspension is implemented, it prevents issuance of any payments to providers or suppliers while the suspension is in place. CMS data files that come from our claims processing systems will include claims that appear as "paid" because those claims were determined to be "payable" by Medicare, but that does not mean that Medicare actually paid out that money. In other words, a claim may appear as "paid" regardless of whether payments are issued, if payments are held by a payment suspension pending an investigation, or if payments are applied to a pre-existing debt.

CMS works closely with the HHS Office of Inspector General Office of Investigations and the Department of Justice to investigate health care fraud schemes, referring cases to law enforcement partners, as appropriate. If CMS determines an overpayment was made, the agency recovers those funds. CMS also has authority to take other administrative actions, such as revoking a provider's ability to participate in Medicare programs and/or making referrals to law enforcement to pursue criminal and civil charges.

In early 2023, CMS detected a suspicious increase in billing for urinary catheters which, as of July 2024, exceeded $4 billion. As potentially fraudulent suppliers began to bill for urinary catheters the agency quickly took action to prevent money from the Medicare trust fund from being released to them. This prevented over 99% of payments for Medicare payable claims from being issued to 15 potentially fraudulent suppliers. These identified suppliers were responsible for over 89% of billings to Medicare for urinary catheter supplies between January 1, 2023 and July 6, 2024. CMS is working closely with law enforcement to support their investigations and ensure individuals and companies are subject to civil and criminal penalties, if appropriate. In addition, CMS revoked Medicare enrollments of these 15 suppliers to prevent future improper billings. Revocations prevent the provider/supplier from re-enrolling in Medicare for up to 10 years. CMS and its contractors have used the lessons learned to improve monitoring and response.

CMS implements several program integrity efforts and applies advanced data analytics to detect and prevent fraudulent activities. As described above, we also take swift action to address suspected fraud, including preventing payments from being made and taking revocation action to prevent suppliers from billing for dates of services on or after the revocation effective date.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct DME MACs to recover $11,399 in overpayments made to suppliers for the 15 sample items that did not meet Medicare requirements.

CMS Response

CMS concurs with this recommendation. CMS will direct the MACs to recover identified overpayments associated with OIG's medical reviews consistent with relevant law and the agency's policies and procedures.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct DME MACs to, based on the results of this audit, notify appropriate suppliers (i.e. those for whom CMS determine this audit constitutes credible information of potential overpayments) so that the suppliers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

CMS Response

CMS does not concur with this recommendation. CMS previously requested that this recommendation be removed. OIG identified a limited number of suppliers (12) as having errors and this recommendation would require the identified suppliers to conduct a medical and/or documentation review of each of their associated claims. CMS does not believe that this would be an efficient use of the 60-day rule, and that the return on investment would be low. CMS continues to request that this recommendation be removed.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct DME MACs to perform additional medical reviews of intermittent urinary catheter and sterile catheter kit claims, which could have saved Medicare up to an estimated $35,079, 833 for our audit period.

CMS Response

CMS concurs with this recommendation. CMS will notify the DME MACs of the OIG's audit so that they may evaluate the risk associated with these claims as part of their annual Improper Payment Reduction Strategy.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct DME MACs to provide additional education to suppliers on documenting eligibility for intermittent urinary catheters and sterile catheter kits. For example, CMS could emphasize the following:

- Medical records that list only a diagnosis without adequate documentation of an enrollee's inability to use a straight-tip catheter are insufficient to support medical necessity for use of a curved-tip catheter.
- Notations of urinary tract infections in medical records are insufficient to support that an enrollee is eligible for sterile catheter kits, and there must be documentation supporting that the enrollee: (1) had two instances of urine cultures with greater than 10,000 colony-forming units of a urinary pathogen during a 12-month period before initiation of a sterile catheter kit and (2) had one or more qualifying concurrent conditions.
- There must be documentation supporting that a supplier contacted an enrollee before dispensing a refill of catheters or sterile catheter kits.

CMS Response

CMS concurs with this recommendation. CMS will direct the DME MACs to continue to provide education consistent with the payment and coverage policies.

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