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COMMENTARY

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OIG RECOMMENDS 'HIGH RISK/LOW REWARD' STRATEGY ON INTERMITTENT CATHETERS

SUMMARY

The OIG recently recommended to CMS that it follow a 'high risk/low reward' strategy on paying for intermittent catheters for Medicare beneficiaries. OIG argued that it had identified approximately $200 Million in Medicare payments that constituted "potential Medicare savings and supplier profits" and urged CMS to recapture some unspecified portion of these payments through the DMEPOS competitive bidding program or by using its "inherent reasonableness" authority to adjust the payments when it determines that the standard rules for calculating payment amounts will result in grossly deficient or excessive payment amounts.

The OIG report fails to support its recommendation that CMS cut prices for intermittent catheters:

- The reward in payment reductions that CMS might achieve is too small to risk the potential high cost of following OIG's recommendations.
    - By slashing catheter prices, CMS will reduce the share of beneficiaries receiving intermittent catheters
    - OIG ignored the significant risk this will create, the risk of dramatically increasing CMS payments for treating the illnesses and injuries that could befall Medicare beneficiaries denied critical access to catheters
    - Using OIG's spending and saving estimates and data from previously published studies on Medicare spending for other DME, *we estimate that to achieve a potential maximum saving of $198 Million on providing catheters, CMS would risk increasing treatment costs by about $1 Billion*
- OIG ignored the reality that DMEPOS competitive bidding has run its course and is no longer an effective tool to manage Medicare pricing
- 'Inherent reasonableness' is a risky process that has only been attempted twice by CMS (both times more than 20 years ago), once on a product that was too early in development to be effective and once when its implementation was blocked by Congress
- OIG continues to encourage CMS to make critical and risky beneficiary decisions based on data that is severely dated and not reliable to assess current economic conditions

- OIG casts doubt on its own recommendations, arguing that it is based on unreliable industry studies and estimates of supplier costs

THE OIG REPORT

In an August 2022 report entitled *Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year*, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services recommended that the Centers for Medicare and Medicaid Services (CMS) take a high potential risk for low potential reward approach to paying for intermittent urinary catheters for Medicare beneficiaries.

OIG's rationale for analyzing Medicare spending on catheters was the failure of CMS to respond to a 2018 Medicare Payment Advisory Commission (MedPAC) report relying on 2015 data that recommended that CMS include intermittent catheters in the next competitive bidding round.

OIG focused its analysis on the differential between Medicare spending and supplier costs by sampling 600 Medicare claims from FY 2020, for the three billing categories of intermittent urinary catheters. From the sampled claims data, OIG estimated suppliers' acquisition costs at $121 million.

From Medicare payment data, OIG found that CMS and its Medicare beneficiaries paid suppliers $407 million for intermittent urinary catheters in fiscal year 2020, some 3.4 times the acquisition costs. From this, OIG concluded that "the magnitude of the differences between Medicare reimbursements and suppliers' acquisition costs indicates that Medicare and its beneficiaries can achieve substantial savings while allowing for other costs."

OIG acknowledged that suppliers also face other costs beyond the cost of acquiring catheters and need an opportunity to make a profit from their sales. While recognizing this need to achieve a profit margin, OIG still asserted that the magnitude of the differences between Medicare reimbursements and suppliers' acquisition costs was so large that Medicare and its beneficiaries could still realize substantial savings while allowing for other costs and profits.

To provide an example of the potential for savings, OIG attempted to estimate suppliers' other costs. It used data in a 2016 report from the home health care industry that was not specific to catheters. The report estimated that for every dollar spent on acquisition costs, suppliers spent an additional 72 cents in other costs. OIG used this data to estimate that other costs amounted to $88 Million, for a total cost of $209 million with no profit for suppliers included. That meant that there were $198 million left in potential Medicare savings and supplier profits. OIG also argued that the industry report overstating suppliers' other costs, implying an industry bias and arguing that other costs would be lower because most catheters were delivered by mail.

DISCUSSION

High Potential Risk -

The reward in payment reductions that CMS might achieve is too small to risk the potential high cost of following OIG's recommendations.

OIG and CMS typically diminish the risk that beneficiaries will lose access to DME when prices are cut with dismissive pronouncements like the one that appeared in the OIG report: 'CMS should take steps to lower Medicare's payment rates for these catheters while maintaining beneficiaries' access to the catheters that best serve their medical needs'. While this should certainly be a primary goal for CMS pricing exercises, it is more a platitude regularly used to justify price cuts.

There is an inherent risk that by cutting payments, CMS will fail to protect beneficiary access to needed DME. By slashing catheter prices, CMS will reduce the share of beneficiaries receiving intermittent catheters and increase resulting treatment costs.

A considerable portion of DME spending cuts is achieved by reducing the share of beneficiaries using DME. One recent analysis calculated that competitive bidding cost reductions resulted in an 11% decrease in beneficiaries receiving DME.[1] When any beneficiary loses access to needed DME, the result is a leveraged increase in payments for treating the very illnesses and injuries that result from not having the DME. From Medicare spending studies published in 2021 and 2022, the leverage factors can range from 26:1 to 66:1.[2]

In its report, OIG completely failed to consider the potential cost of treating illnesses and injuries that might result from failure to provide needed DME to beneficiaries due to implementing drastic price reductions. Beneficiaries in need of intermittent catheters include significant groups with spinal cord injuries and a range of neurological conditions. For this significantly vulnerable segment of beneficiaries, the loss of access to needed DME will most certainly result in immediate and severe medical conditions with expensive treatment costs.

OIG did acknowledge some of the problems that can occur, stating, "Without catheterization, urinary retention can block the flow of urine from the kidneys and lead to swelling and kidney damage. Kidney damage, resulting from UTIs or bladder overdistension, can progress to chronic kidney disease and kidney failure". Yet OIG failed to take the costs of treating these problems into account.

Using OIG's spending and saving estimates and data from previously published studies on Medicare spending for other DME[3], *we estimate that to achieve a potential maximum saving of $198 Million on providing catheters, CMS would risk increasing treatment costs by about $1 Billion*[4].

Competitive Bidding -

OIG has ignored the reality that the DMEPOS competitive bidding program has run its course and is no longer an effective tool to manage Medicare pricing.

Over the past decade, CMS has focused its efforts on cost cutting, attempting to squeeze as many dollars out of Medicare spending for DME as it could, often without due regard to the negative risk and impact on beneficiaries. CMS chose to slash DME spending and attempted to eliminate the fraud they saw in the system. Its mission was to cut costs through the competitive bidding program, and it did generate some savings and reduce fraud and waste in the system.

But at the same time, CMS totally missed the big opportunity, orders of magnitude larger -- the power of *investing* in DME to reduce its massive spending to treat the illnesses and injuries caused by not providing critical DME to beneficiaries when they needed it. Studies on Medicare spending in the competitive bidding era have shown that every dollar wisely invested in providing DME could have reduced spending on treatment by orders of magnitude more, 26 to 66 times more. CMS focused on cutting DME spending when it should have gone after the bigger prize, saving treatment costs.

Competitive bidding was a contrived concept destined to fail. By the end of the last decade, competitive bidding had effectively stalled out. The 2019 and 2021 rounds fizzled. The 2019 round was 'delayed'[5] as the program approached what may be its natural end – CMS was no longer able to squeeze any more cost out of the system. The 2021 round, characterized in the trade as a 'failed round'[6], was limited to only two product categories—off-the-shelf (OTS) back braces and OTS knee braces. Competitive bidding no longer works.

At the same time, competitive bidding drove down the number of DME suppliers. Supplier locations operating during the decade of competitive bidding dropped by about 40%[7], depending on the data source. Reductions were even more drastic in some of the individual DME categories, where the number of suppliers plummeted nearly 50%.[8]

Inherent Reasonableness –

'Inherent reasonableness' has only been used once by CMS. In 1995, it used the theory to change pricing on a product line [continuous glucose monitors] that at the time was very early in its development cycle and too soon for downward price regulation. Even today, continuous glucose monitoring has still not achieved mainstream status and has found use in only limited situations. A 2nd attempt by CMS to utilize inherent reasonableness to lower prices never got out of the starting gate and was overturned by Congressional action in 1999. Reliance on inherent reasonableness is a risky and unsupported path for CMS to follow.

Reliance on old data from a different healthcare era -

OIG continues to encourage CMS to make critical and risky beneficiary decisions based on data that is severely dated and not reliable to assess current economic conditions.

OIG references a 1999 statement by CMS that 67% is the upper limit of acceptable supplier markup, but this statement is based on data analyzed by CMS that was from 24 to 33 years old (1989 -1998).

The industry study OIG used to construct its example of the supplier costs is six years old. The data used in the Med PAC report that was the basis of OIG's new recommendations was from 2015.

The overriding theme here is that OIG continues to encourage CMS to make critical and risky beneficiary decisions based on data that is severely dated and not reliable to assess current economic and healthcare industry conditions. The risk to Medicare beneficiaries is significant here and OIG needs to stop this practice.

OIG's own analysis is unreliable –

CMS should not rely on an OIG report that is by its own admission unreliable to disrupt current pricing for intermittent catheters. In the August 2022 report, OIG casts doubt on its own recommendations, admitting that its calculations and conclusions are based on unreliable industry studies and estimates of supplier costs.

The bottom line –

For the numerous reasons set out in this Commentary, CMS should not follow the recommendations made by OIG in its August 2022 report. To do so would set CMS off on yet another downward spiral to cut DME spending costs that may result in relatively small amounts of saving at the very large risk of harming Medicare beneficiaries. Instead, CMS should spend its time and efforts developing programs that will reduce the dramatically higher treatment costs that result from not providing intermittent catheters to beneficiaries when they are needed.

"To achieve a potential maximum saving of $198 Million on providing catheters, CMS would risk increasing treatment costs by about $1 Billion"

[1] Ji, *The Impact of Competitive Bidding in Health Care: The Case of Medicare Durable Medical Equipment* (2019) ********scholar.harvard.edu/files/yunan/files/dme.pdf

[2] Leitten, Competitive Bidding - A Decade Focused on the Wrong Prize, The Case for Medicare Investment in DME in 2021 https://www.vgmdclink.com/uploads/Document-Library/61cb718f762181b1af06911ee8dfef04.pdf and Competitive Bidding: Pressure Sore, Urological and Diabetes Equipment & Supplies The Expanded Case for Medicare Investment in DME in 2022, **********.vgm.com/webres/File/Gov%20Docs/2022%20LEITTEN%20STUDY.pdf

[3] Id.

[4] OIG estimates that CMS spent $407 Million on reimbursements for intermittent urinary catheters in FY 2020 and that the potential savings and supplier profit for the same period is $198 Million. The Leitten studies (Note 2) estimate that the lower range for the ratio of treatment costs to DME purchases is 26:1. Using the OIG spending estimate and the 26:1 treatment cost ratio, one can estimate that annual treatment costs related to losing access to intermittent catheters would be $10.6 Billion. This is approximately 1/3 of the $32.5 Billion projected Medicare spending on urinary complications and appears to be a reasonable approximation of catheter-related treatment spending. The Ji article (Note 1) calculates the reduction in beneficiaries receiving DME as a result of programmed price cutting at 11%. Multiplying this percentage by the $10.6 Billion estimated treatment spending results in an estimate of $1.17 Billion in at risk treatment cost increases.

[5] Kopf, HME BUSINESS, *CMS DELAYS COMPETITIVE BIDDING ROUND 2019*, February 8, 2017 ********hme-business.com/articles/2017/02/08/2019delay.aspx

[6] Taylor, *Medicare DME competitive bidding in doubt after failed round: analysts*, MedTechDive, Feb. 8, 2021 **********.medtechdive.com/news/medicare-dme-competitive-bidding-in-doubt-after-failed-round-analysts/594675/

[7] Higley, HME Past, Present & Future: State Of The Industry / Benchmarking Update / Round 2021 & Beyond, **********.vgm.com/communities/hme-past-present--future-state-of-the-industry--benchmarking-update--round-2021--beyond/

[8] Pigg, *Competitive bidding is here to stay for medical suppliers*, The Hill (2018) ********thehill.com/blogs/congress-blog/healthcare/413837-competitive-bidding-is-here-to-stay-for-medical-suppliers