

MEMORANDUM

Date: July 17, 2017

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Subject: CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment

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OVERVIEW

On July 17, 2017, the U.S. Government Accountability Office (GAO) published the report titled, "[CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment](#)." For the study, GAO interviewed 21 stakeholders to understand the market for and benefits of disposable devices that are potential substitutes for DME. GAO found that disposable equipment can have multiple benefits, including better health outcomes and improved savings, but CMS' DME coverage benefit limitation discourages manufacturers from developing new disposable devices. GAO recommends CMS to evaluate the potential savings disposable devices can provide and if appropriate, pursue legislative authority to expand coverage.

EXAMPLES OF POTENTIAL DISPOSABLE SUBSTITUTES

The following are some of the potential disposable substitutes that the GAO reviewed for the report.

- Infusion pump substitutes:
  - Ambulatory infusion pump that has a 1-year life expectancy.
  - Elastomeric pump which is a single-use device.
- Insulin Pump substitutes:
  - A completely disposable insulin pump that can last 24 hours.
  - Insulin pump with disposable and durable components that can last 3 days
- Blood glucose monitor substitute:
  - A completely disposable blood glucose monitor that can be discarded after all 50 test strips that comes with the device have been used.
- Sleep apnea device substitutes:
  - Disposable valve that goes into a patient's nose that is discarded after one use.
  - Disposable micro-CPAP aimed to last 8 hours.
- Nebulizer substitute:
  - Disposable nebulizer that can last a year.

BENEFITS OF DISPOSABLE DME ACCORDING TO STAKEHOLDERS

GAO spoke with 21 stakeholders, which included manufacturers, beneficiary groups, providers, and insurance representatives. More than half of the stakeholders discussed the benefits of using disposable devices.

Of the 21 stakeholders, 12 stated how patients sometimes prefer the disposable devices over the DME because it improves their quality of life due to usability, such as the device is lighter and quieter.

Nine stakeholders discussed how disposable devices can result in better health outcomes for patients because the devices were developed to help patients who are not using their DME as prescribed.

Twelve stakeholders shared disposable devices can create a potential savings for Medicare. For patients that only need to use a specific device for a short period can be prescribed a disposable device instead of paying for a durable equipment. In addition, disposable devices generally do not require cleaning and maintenance that is usually needed with DME.

LIMITATIONS OF DISPOSABLE DEVICES ACCORDING TO STAKEHOLDERS

Stakeholders and DME MACs stated there are a few studies that revealed limitations to the health outcomes and savings associated with disposable equipment. There are also medical situations where DME is preferred, such as when medication delivery has to be specific. Four of the 21 stakeholders stated savings may not be achieved for all disposables and DME may be more economical.

STAKEHOLDER INCENTIVES/DISINCENTIVES FOR DISPOSABLE DEVICES

There are several incentives for developing disposable substitutes. Due to the growing patient population, there is a higher demand for certain types of devices Twelve of the 21 stakeholders shared that there is an international market for disposable devices.

Thirteen of the 21 stakeholders stated that the lack of Medicare coverage for disposables was a disincentive in developing more products. Of the thirteen, 9 stakeholders (four of them manufacturers) stated Medicare coverage is a barrier to developing disposable items. However, there are some disposable items that are covered by Medicaid.

GAO identified three ways CMS can expand coverage to disposable items, the table below provides the method, and under each method, CMS would need to review reimbursement options and authority it falls under to make that change.

**Table 2: Possible Options for Covering Disposable Durable Medical Equipment (DME) Substitutes**

Medicare benefit category	Authority	Reimbursement options
DME benefit	Regulatory change could redefine “durable” to accommodate substitutes with shorter life expectancy, but congressional action likely necessary for single and short-term use devices	Use current fee schedule or a reduced percentage of the fee schedule amount <b>or</b> Establish payment through the competitive bidding program
Home health benefit	Congressional action required	Establish a separate payment for home health beneficiaries using disposable DME substitutes <b>or</b> Adjust the home health bundle to include disposables
Newly established benefit for disposable devices	Congressional action required	Would depend on congressional action taken in establishing the new benefit

Source: GAO analysis of applicable laws and regulations. | GAO-17-600

Note: The possible options presented in this table are not intended to be an exhaustive list.

CONCLUSION

Disposable devices may provide potential benefits, both for beneficiaries and for the Medicare program. Due to reasons such as growing patient population and advancement in technology, the need for disposable devices is growing. However, Medicare’s benefit and the definition of DME limits

manufactures from developing more disposable devices. CMS believes the definition of DME does not need to be changed, but GAO believes disposable items can fall under the DME benefit, home health benefit, or CMS can create a new benefit specifically for disposable items. GAO references that the federal internal control standards want management to prepare to make great changes using forward thinking process and without considerations for disposable items, CMS may miss the opportunity for potential savings and increased improved health outcomes.

### GAO RECOMMENDATIONS

GAO recommends CMS Administrator to review the potential cost-savings from using disposable devices in the place of DME. GAO recommends CMS to pursue a legislative change for disposable device coverage depending on CMS' findings.

### HHS/CMS RESPONSE

HHS did not take a position but stated that only Congress can make changes to include disposable devices. CMS responded that it is too early to do a study on the potential savings of disposable devices.

### GAO RESPONSE TO HHS/CMS RESPONSE

GAO agrees that HHS may need to take a legislative approach to make this change. However, GAO disagrees with CMS that it is premature to cost-savings study.

### AAH NOTES

**The GAO interviewed AAH for this report in November 2016. During the meeting, AAH shared the industry's concerns with incentive for manufacturers to develop disposable technologies and the challenges with determining when disposable products versus durable products should be dispensed. AAH further indicated that the creation of a disposable benefit should be part of the DMEPOS space as these beneficiaries would be seeking either the disposable or durable technology within the required LCD and NCD requirements that exist today.**