

Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes  Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



## Virginia Department of Planning and Budget Economic Impact Analysis

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**12 VAC 30-50 Amount, Duration, and Scope of Medical and Remedial Care and Services**  
**Department of Medical Assistance Services**  
**Town Hall Action/Stage: 4777 / 8108**  
April 26, 2018

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### **Summary of the Proposed Amendments to Regulation**

On behalf of the Board of Medical Assistance Services, the Director of the Department of Medical Assistance Services (DMAS) proposes to: 1) eliminate the requirement that enteral nutrition (EN) be the Medicaid beneficiary's primary or sole source of nutrition in order to cover EN, 2) amend text to clarify that the use of implantable pumps for delivering home infusion therapy is permitted and covered, 3) reduce requirements concerning the delivery ticket, and 4) clarify the process for providing replacement durable medical equipment and supplies (DME) to Medicaid beneficiaries who have lost DME or had DME destroyed as a result of a natural disaster.

### **Result of Analysis**

The benefits likely exceed the costs for all proposed changes.

### **Estimated Economic Impact**

#### *Enteral Nutrition*

EN is defined as "any method of feeding that uses the gastrointestinal tract to deliver part or all of an individual's caloric requirements. Enteral nutrition may include a routine oral diet, the use of liquid supplements, or delivery of part or all of the daily requirements by use of a tube

(tube feeding).” EN can be effective in helping prevent malnutrition for patients with a variety of conditions.<sup>1</sup> It has been found to reduce hospital complications, duration of stay, and mortality.<sup>2</sup>

The current regulation requires that EN be the primary or sole source of nutrition in order to qualify for coverage. Pursuant to guidance from the federal Centers for Medicare and Medicaid (CMS), the Director proposes to eliminate the requirement that enteral nutrition EN be the Medicaid beneficiary’s primary or sole source of nutrition in order to qualify for coverage. DMAS estimates the annual cost of this proposed change to be \$2,308,065, half to be paid with state funds and half to be paid with federal funds. As described above, expanding the use of EN can have significant health benefits.

#### *Home Infusion Therapy*

The current regulation defines home infusion therapy as the administration of intravenous fluids, drugs, chemical agents, or nutritional supplements. The Director proposes to amend the definition of home infusion therapy to indicate that it can be administered either intravenously or through the use of an implantable pump. In practice, the use of an implantable pump has been covered.<sup>3</sup> Thus, this proposed amendment would effectively just be a clarification for readers of the regulation. Nevertheless, it would be beneficial in that it would reduce the likelihood of confusion over whether implantable pumps are covered.

#### *Delivery Ticket Components*

Under the current regulation, DME providers must include the Medicaid beneficiary’s name and Medicaid number or date of birth on the delivery ticket. Further, DME providers must include the serial number(s) or the product numbers of the DME or supplies. The Director proposes to: 1) allow DME providers the option of having a unique identifier (e.g. an individual’s medical record number) instead of the Medicaid number or date of birth on the ticket, and 2) no longer require serial number(s) or the product numbers on the ticket. This proposal reduces the burden on DME providers.

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<sup>1</sup> See Thomas D “Enteral Tube Nutrition” *Merck Manual* February 2017.

<sup>2</sup> See Stroud M, Duncan H, Nightingale J “Guidelines for enteral feeding in adult hospital patients” *Gut* 2003;52:vii1-vii12.

<sup>3</sup> Source: Department of Medical Assistance Services

### *Replacement DME*

The current regulation does not address the process for providing replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed due to a natural disaster. The Director proposes to add a section to the regulation to identify the process and requirements for providing replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed due to a natural disaster. According to DMAS, the proposed language matches how this is currently done in practice. However adding the section would likely be beneficial in that it helps inform Medicaid recipients, Medicaid enrolled providers, and other interested parties who may not be specifically aware of the process and requirements.

### **Businesses and Entities Affected**

The proposed amendments affect the approximate 1,400 Medicaid-enrolled DME providers,<sup>4</sup> and Medicaid recipients. Most providers would qualify as small businesses.

### **Localities Particularly Affected**

The proposed amendments do not disproportionately affect particular localities.

### **Projected Impact on Employment**

The proposal to cover EN even when it is not the sole or primary source of nutrition would increase demand for tubing and other supplies associated with EN. There may consequently be a moderate increase in employment at firms that provide these supplies.

### **Effects on the Use and Value of Private Property**

The proposal to cover EN even when it is not the sole or primary source of nutrition would increase demand for tubing and other supplies associated with EN. There may consequently be a moderate increase in the value of firms that provide these supplies.

### **Real Estate Development Costs**

The proposed amendments do not affect real estate development costs.

### **Small Businesses:**

#### **Definition**

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and

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<sup>4</sup> Data source: Department of Medical Assistance Services

(ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

### **Costs and Other Effects**

The proposals to allow DME providers the option of having a unique identifier instead of the Medicaid number or date of birth on the delivery ticket, and to no longer require serial number(s) or the product numbers, would moderately reduce costs for small DME providers.

### **Alternative Method that Minimizes Adverse Impact**

The proposed amendments do not adversely affect small businesses.

### **Adverse Impacts:**

#### **Businesses:**

The proposed amendments do not adversely affect businesses.

#### **Localities:**

The proposed amendments do not adversely affect localities.

#### **Other Entities:**

The proposed amendments do not adversely affect other entities.

### **Legal Mandates**

**General:** The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

**Adverse impacts:** Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving

the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.