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Proposed Mandate Evaluation: Coverage of Ostomy Equipment and Supplies

Prepared for the Maryland Health Care Commission
Pursuant to Insurance Article 15-1501
Annotated Code of Maryland



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Mandated Coverage of Ostomy Equipment and Supplies

Insurance Article § 15–1501, Annotated Code of Maryland, requires that the Maryland Health Care Commission (Commission) annually assess the medical, social and financial impact of proposed mandated health insurance services that failed to pass during the preceding legislative session or that are submitted to the Commission by a legislator by July 1 of each year. The assessment reports are due to the General Assembly annually by December 31.

Mercer and its sibling company, Oliver Wyman Actuarial Consulting, Inc., (collectively called “Mercer” in this report) have been contracted as the Commission’s consulting actuary. Mercer has prepared this evaluation for the single proposed newly mandated benefit: coverage of ostomy equipment and supplies.

This report includes information from several sources to provide more than one perspective on the proposed mandate. Mercer's intent is to be unbiased. As a result, the report contains some conflicting information. Although we include only sources that we consider credible, we do not state that one source is more credible than another. The reader is advised to weigh the evidence.

The Affordable Care Act (ACA) describes a broad set of benefits that must be included in any essential health benefits (EHB) package. In its December 2011 bulletin, the Department of Health and Human Services (HHS) provided guidance on the types of health benefit plans each state could consider when determining a benchmark EHB for its residents. Maryland has chosen the CareFirst Open Access HMO small group health benefit plan as the state’s benchmark plan, which reflects all of the pre-2012 Maryland mandates applicable to the Comprehensive Standard Health Benefit Plan (CSHBP). This is important because the ACA also requires states to fund the cost of any mandates that are not reflected in the state-specific EHBs for policies purchased through the Health Benefit Exchange.

Senate Bill 671 of the 2014 legislative session requires health insurers, non-profit health service plans and health maintenance organizations (collectively known as carriers) that provide hospital, medical or surgical benefits to provide coverage for all medically appropriate and necessary equipment and supplies for the treatment of ostomies. Examples of such equipment and services include – but are not limited to – flanges, collection bags, clamps, irrigation devices, sanitizing products, ostomy rings, and ostomy belts. In this instance, “ostomy” includes colostomy, ileostomy and urostomy.

The bill applies to all policies and contracts that are issued, delivered or renewed in Maryland on or after October 1, 2014, but exempts plans that provide EHBs under ACA, including qualified health plans offered in the Maryland Health Benefit Exchange as well as all non-grandfathered health benefit plans offered outside the Exchange to individuals and small employers.

Prior to 2014, the costs of ostomy equipment and supplies were covered by most – but not all – policies in Maryland. In some instances, the employer may decide whether or not to cover these costs. The proposed mandate would require the minority of contracts issued in Maryland that do not cover such equipment and supplies to do so. Note that only one state (Connecticut) currently mandates coverage of ostomy equipment and supplies.¹

¹ Miscellaneous Mandates, NAIC Compendium of State Laws on Insurance Topics, National Association of Insurance Commissioners, November 2013.

Medical Impact

In this section, we answer questions regarding ostomy supplies.

- **What are the risks of failing to cover ostomy equipment and supplies?**
- **What are the appropriate standards of care for patients?**
- **How are ostomy equipment and supplies typically covered?**

Medical Background

Ostomy is an umbrella term that describes several types of surgeries that create an opening from an area inside the body to the outside for the discharge of body wastes. The opening, which is called a stoma, is created to treat certain diseases of the digestive and urinary systems and can be either temporary (when an organ needs time to heal) or permanent (when an organ must be removed).² It is necessitated by a number of different conditions – including inflammatory bowel disease (such as Crohn’s disease or ulcerative colitis), cancer, birth defects and injury. People of all ages can be affected.³

An ostomy creates a new way for waste to leave the body. For example, in an ileostomy, the bottom of the small intestine is attached to the stoma and bypasses the colon, rectum and anus; in a colostomy, the colon is attached to the stoma and bypasses the rectum and anus; and, in a urostomy, the tubes that carry urine to the bladder are attached to the stoma and bypass the bladder.⁴

An ostomy, regardless of the type, requires various supplies and equipment to (1) properly care for the stoma, and (2) collect and dispose of body waste. Typical supplies include a barrier (wafer) or faceplate, which acts as an interface between the patient’s skin and the pouching system; pouches, for collecting stoma output; pastes, which serve as a protective layer and sealant beneath ostomy appliances and are applied directly to the skin; and various other supplies that allow for proper use and hygiene – including tapes, clamps, flanges, and absorbent materials. Finally, irrigation equipment is sometimes used to flush out the bodily waste collected in the ostomy.⁵

The supplies required, the necessary quantities, and the product prices vary with the type of ostomy. People with ileostomies (which account for about a third of all ostomies) require the most frequent changes, while individuals with colostomies typically require fewer changes. Some people may require a relatively large number of supplies because of the nature of their surgeries (for instance, those people with severe cases of cancer requiring extensive surgery).⁶

² Chasse, J. B., “Health Insurance – Coverage for Ostomy Equipment and Supplies – Required.” Fiscal and Policy Note, Department of Legislative Services, Maryland General Assembly, 2014 Session.

³ “Metro Maryland Ostomy Association’s Top Legislative Initiative Introduced in the Maryland Senate.” PRWeb, February 3, 2014.

⁴ Connecticut Mandated Health Insurance Benefits Reviews, 2010, vol. I, University of Connecticut, January 2011, pp. 41-56.

⁵ Connecticut Health Insurance Benefit Reviews, 2010.

⁶ Connecticut Health Insurance Benefit Reviews, 2010.

The Risks

The primary risk is financial, not medical, and is addressed in the next section of this report.

Standards of Care

Individuals who have had ostomies must use certain equipment and supplies, some temporarily and some permanently. No other treatments, methods, or procedures are available that could serve as substitutes.⁷

Coverage

There are a number of potential funding sources to cover the costs of ostomy equipment and supplies. Sources include Medicare, public programs administered by charities, public programs administered by public schools, public health programs, Medicaid, and private insurance.⁸

In 2008, there were 9,662 discharges from US hospitals with colostomy procedures noted as the principle procedure. Forty-six (46) percent of the claims were paid by Medicare, 32 percent were paid by private insurance, and 15 percent were paid by Medicaid. The same year, there were 8,084 discharges from US hospitals with ileostomy/enterostomy procedures noted as the principle procedure. Forty-four (44) percent of the claims were paid by Medicare, 37 percent were paid by private insurance, and 13 percent were paid by Medicaid.⁹

Medicare Medicare covers ostomy supplies and equipment as durable medical equipment (DME) under Medicare Part B. To qualify for Medicare Part B benefits, the ostomate must have Part B coverage, a physician's documentation of the need for the supplies and equipment, and a prescription clearly stating which supplies and equipment are needed. For most Medicare Part B insureds, after the satisfaction of a calendar year deductible (\$147 in 2014), Medicare pays 80 percent of the allowable fee and the individual pays 20 percent. Participants in Medicare Advantage Plans may be entitled to additional benefits, but there may be limitations on the sources of these products.¹⁰

Medicare allows up to a three-month supply of ostomy products at one time, unless there is medical necessity for more. Typical Medicare ostomy products and monthly quantity guidelines are as follows:

- Convex inserts 10
- Closed one-piece pouches 20
- Closed two-piece pouches 60
- Drainable one-piece pouches 20
- Drainable two-piece pouches 20
- Irrigation bags and tubing 2/six months
- Irrigation cones 2/six months
- Irrigation sleeves 4
- Non-sterile gauze pads 60
- Ostomy belt 1
- Ostomy wafers/barriers 20

⁷ Connecticut Health Insurance Benefit Reviews, 2010.

⁸ Ibid.

⁹ Ibid.

¹⁰ Flores, G. "Medicare Coverage of Ostomy Supplies." Shield HealthCare Community, updated September 2011, accessed May 26, 2014.

- Pouch deodorant 4 oz.
- Skin barrier liquid or spray 2 oz.
- Skin barrier wipes or swabs 150/six months
- Stoma caps 31¹¹

These products and monthly quantities are just guidelines. The needed amount of supplies varies. Individuals who have had an ileostomy will require the most frequent changes, while those with colostomies require less frequent changes. In some instances, the need for supplies may exceed the quantity guidelines, and physician certification of medical necessity may be needed.¹²

Medicaid Nationally, Medicaid is the third largest payer of ostomy products, trailing only Medicare and private insurance. In Maryland, Medicaid covers ostomy equipment and supplies as durable medical equipment/disposable medical supplies and provides an extensive array of ostomy products. There is an approved list of products that is updated quarterly. Currently, Maryland pays 85 percent of Medicare’s April 2013 fee schedule for these products unless the program has assigned its own rate to an item. There are no limits on the quantities as long as they are medically necessary, and there are no copays or coinsurance. To qualify, the beneficiary must have a doctor’s prescription and the suppliers must be registered with the State. (Medicaid will not pay for products from unauthorized suppliers.)¹³

Private Health Insurance Private health insurance is the second largest payer of ostomy products.¹⁴ In Maryland, substantially all small group and large group fully insured contracts cover medically necessary ostomy equipment and supplies. Reimbursement levels are subject to the contracts’ benefit structures.

Social Impact

In this section, we address the following questions:

- **To what extent will the proposed mandate generally be used by a significant portion of the population?**
- **To what extent is the insurance coverage already available?**
- **To what extent does the lack of coverage result in individuals’ avoiding necessary health care treatments?**
- **To what extent does lack of coverage result in unreasonable financial hardship?**
- **What is the level of public demand for these services?**
- **To what extent is the mandated health insurance service covered by self-funded employers in the State with at least 500 employees?**

Social Background

While the risks are primarily financial, the implications are social. Numerous reports indicate that many ostomy patients feel a certain stigma and are often socially withdrawn to some degree. Equipment and supplies allow ostomy patients to enjoy a higher quality of life, but costs can be a barrier. A study of veterans with ostomies found that those individuals who had

¹¹ Ibid.

¹² Connecticut Health Insurance Benefit Reviews, 2010.

¹³ Ibid.

¹⁴ Connecticut Health Insurance Benefit Reviews, 2010.

difficulty paying for ostomy supplies scored lower on a quality-of-life questionnaire.¹⁵ Another study shows a correlation between distress over obtaining ostomy supplies and poor long-term adjustment.¹⁶

Prevalence

Age is an important consideration in estimating prevalence. Although people of any age can be affected, a 1998 study indicated that the average age of someone with an ostomy was 68.3 years; (colostomy: 70.6 years; ileostomy: 67.8 years; and urostomy: 66.6 years). These estimates indicate that the “average” American with an ostomy is eligible for Medicare. As the US population ages, the number of individuals requiring ostomies (and the necessary equipment and supplies) can be expected to increase.¹⁷

Estimates vary regarding the prevalence of ostomies. In 2009, the United Ostomy Associations of America estimated that 650,000 to 730,000 Americans, or about 0.22% of the population, have some type of stoma.¹⁸ Also, 2008 estimates indicated that there are 113,000 ostomies each year – over 30% of which are temporary.¹⁹ Based on a 2013 US population estimate of over 316 million,²⁰ approximately 695,000²¹ people have some type of stoma today. Among Maryland’s population of about 6,000,000,²² about 13,200²³ may have some type of stoma.

Coverage

The Mercer internal database shows the average percentage of the population covered by group health benefit plans in Maryland for the 2010 - 2012 time period to be 0.11%.²⁴ Mercer also has access to the National Association of Insurance Commissioners (NAIC) database for calendar year 2013. The Supplemental Health Care Exhibits (SHCE) of the 2013 statutory

¹⁵ Coons, S.J., “Overall Quality of Life and Difficulty Paying for Ostomy Supplies in the Veterans Affairs Ostomy Health-Related Quality of Life study: An Exploratory Analysis.” *Medical Care* 45(9): 891-5, 2007.

¹⁶ Haugen V., D.Z. Bliss, and K. Savik, “Perioperative Factors That Affect Long-Term Adjustment to an Incontinent Ostomy.” *Journal of Wound, Ostomy and Continence Nursing*, 33(5), 2006.

¹⁷ “Ostomy Statistics: The \$64,000 Question.” *Ostomy Wound Management*, May 31, 2003, accessed May 27, 2014.

¹⁸ Colin Cooke, Researcher, United Ostomy Associations of America, e-mail message to report author, May 29, 2014.

¹⁹ “Ostomy Statistics: July 2008.” The United Ostomy Associations of America, telephone conversation with report author, April 17, 2014.

²⁰ “USA Quick Facts from the US Census Bureau.” US Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Non-employer Statistics, Economic Census, Survey of Business Owners, Building Permits. Last revised March 27, 2014.

²¹ 316,000,000 multiplied by 0.0022.

²² “Maryland Quick Facts from the US Census Bureau.” US Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Non-employer Statistics, Economic Census, Survey of Business Owners, Building Permits. Last revised March 27, 2014.

²³ 6,000,000 times 0.0022.

²⁴ The Mercer internal database includes over \$450 billion in group health plan claims incurred from 2010 to 2012 nationwide. Almost 100 million member years are reflected, including slightly under 1 million Maryland member years over the three year period.

statements show about 833,000 covered lives in large group fully insured plans. Applying the incidence rate of 0.11% to this covered population would indicate there were slightly over 900 ostomates in the large group fully insured market. This may understate the total number of members affected by this law, as grandfathered individual and small group health benefit plans would also be subject to this law.²⁵

If we include all the fully insured lives in all the markets (individual, small group, and large group) reflected in the 2013 SHCE, we would generate an estimate of slightly under 1,400 ostomates. This number is overstated because we know many of the members in the individual and small group markets will migrate to ACA-compliant plans requiring EHBs, which are excluded from this mandate. Therefore, the estimate of lives affected by this proposed mandate is in the range of 900 to 1,400.

As part of this assignment, Mercer surveyed the leading carriers in Maryland. One survey question asked for the number of ostomates for 2012 and 2013 in their insured population. Four of the five carriers responded. The number of ostomates was 1,058 in 2012 and 1,031 in 2013.²⁶ This is within the 900 to 1,400 estimate Mercer independently calculated.

One question on the Mercer carrier survey asked for the percentage of each carrier's products that cover ostomy equipment and supplies. Table 1 summarizes the responses.

Table 1

Percentage of Insured Products Covering Ostomy Equipment and Supplies in 2013

Carrier	Individual	Small Group	Fully Insured Large Group
A	0	100	100
B	85	100	100
C	100	100	100
D	100	100	100
E	100	100	100

Ostomy services and supplies are generally covered as durable medical equipment. Limitations may apply. Durable medical equipment benefits may include separate annual benefit maximums and frequency limitations. Benefits were payable only if prescribed by a physician or other approved health care provider and if the services met the carrier's medical necessity criteria.

Under the ACA, annual and lifetime benefit maximums for EHBs have disappeared, and copayment, coinsurance, out-of-pocket limits, etc., have followed the rules applicable to other services. However, carriers often continue to impose frequency limitations and subject these services to medical necessity rules.

²⁵ "Grandfathered" plans, refers to those individual and small group policies that do not have to comply with the ACA because they were purchased prior to March 23, 2010, and the benefit changes since then have complied with the requirement to maintain grandfather status.

²⁶ The carrier that did not respond reflected less than 5% of the total insured market in 2013, according to the 2013 SHCE reports.

In a survey of Maryland’s health insurance carriers conducted as part of this study, all carriers that responded to this question reported that they cover prescribed, medically necessary ostomy equipment and supplies in substantially all of their products.

Table 2 summarizes the carriers’ responses to the survey.

Table 2

Coverage of Ostomy Equipment and Supplies for Policies in Effect in 2013

Carrier	Coverage of Medically Necessary Ostomy Products
A	No coverage for individual insureds; no limitations for small groups; large group plans may include annual benefit limitations, coinsurance and copays and may require specific vendors
B	No coverage for some individual insureds; annual or no limits for other individual insureds, depending on product; no limitations for small groups; large group plans may include annual limits
C	No specific limitations
D	Medicare durable medical equipment (DME) Medicare Administrative Contractor (MAC) rules with respect to the amount of ostomy supplies; specific vendors preferred
E	Specific vendors required

Some carriers indicated they had eliminated any annual or lifetime maximums to comply with the ACA.

Not all carriers and contracts cover the same ostomy equipment and supplies. Table 3 summarizes the survey responses to the question regarding excluded equipment and supplies.

Table 3

Coverage Exclusions of Ostomy Equipment and Supplies

Carrier	Exclusions
A	No coverage for deodorants, filters, lubricants, tape, appliance clears, adhesive, adhesive remover or any other items not specifically listed
B	None specified
C	None specified
D	No coverage for cleaning brushes, drying racks, pouch covers, room deodorant, rubber bands, rubber gloves, scissors or items which are not medical supplies
E	None specified

All of the carriers indicated that they apply “medical necessity” when determining whether ostomy equipment and supplies will be covered.

Possible Financial Hardship

There are limited data on the costs of these supplies (and the costs vary substantially for the reasons noted), but one estimate is “upwards of \$250/month,”²⁷ and another estimate is \$100 to \$300 per month.²⁸ These costs appear high based on Mercer’s internal database, which shows an **average** monthly cost closer to \$50.²⁹ This same database shows that 90 percent of the members with ostomies had a monthly cost of less than \$110. The monthly cost for the upper most 10 percent of the members was less than \$250. The higher statistics quoted by the other sources may include individuals in Medicaid and Medicare, as well as commercial insurance and uninsured, whereas the Mercer statistics reflect costs associated with group health benefit plans. Since the mandate applies to insured contracts – and primarily large group fully insured contracts – the statistics reflecting group health benefit plan experience would appear to be more appropriate.

As noted, most of the estimates have some form of coverage. The Maryland carriers that were surveyed also estimated the out-of-pocket (unreimbursed) member expenses for ostomy equipment and supplies. The reported numbers shown in Table 4 ranged widely, suggesting potential reporting inconsistency.

Table 4

Estimated Out-of-Pocket Expenses for Ostomy Equipment and Supplies

Carrier	2013 Annual Out-of-Pocket Expenses per Member with Ostomy
A	\$0 median, \$36-\$67 average
B	\$89 average
C	\$488
D	Did not report
E	\$0 median, \$127 average

Coverage by Self-Funded Plans

The carriers who also administer self-funded contracts indicate that their self-insured businesses generally follow the same practices as their fully insured customers.

Based on the results of our review, coverage for ostomy equipment and supplies is almost universal under insured health benefit plans in Maryland – either through Medicare, Medicaid or private insurance.

Financial Impact

In this section, we estimate the cost of enacting the mandated benefit and compare the results of our analysis with those of publicly available sources. Our discussion of the financial impact assumes that ostomy supplies and equipment prescribed by an authorized physician and determined to be medically necessary would be required to be covered.

²⁷ “Metro Maryland Ostomy Association’s Top Legislative Initiative Introduced in the Maryland Senate.”

²⁸ “How Much Does a Colostomy Cost?” CostHelper Health, accessed May 27, 2014.

²⁹ The Mercer internal database includes over \$450 billion in group health plan claims incurred from 2010 to 2012 nationwide. Almost 100 million member years are reflected, including slightly under 1 million Maryland member years over the three year period.

In its analysis, the Department of Legislative Services indicated the proposed bill would not have any impact on the State Employee and Retiree Health and Welfare Benefits Program.³⁰ This implies that these benefits are already part of the existing plan.

One of the survey questions to the major carriers in Maryland was their estimate of the impact on premium of the proposed mandated benefit. In Table 5, we summarize the estimated premium impact of the proposed mandate as reported by the carriers on the survey.

Table 5

Proposed Mandate’s Estimated Impact on Premium

Carrier	Predicted Rate Impact
A	0.1%
B	0.0%
C	0.0%
D	did not estimate
E	0.0%

To obtain an estimate of the magnitude of uncovered ostomy supply claims, we also asked carriers to provide information pertaining to the dollar amount of ostomy supply claims that were denied in 2012 and 2013. It is important to note, however, that claims can be denied for many reasons other than the benefit is not covered. Other reasons for claim denial include but are not limited to an individual’s exceeding any plan limitations; an individual’s failure to use a prescribed vendor (generally limited to HMO plans); the determination that specific supplies are not medically necessary or were not prescribed by a physician; an individual’s ineligibility for membership, etc.

Denied claims for ostomy supplies as a percentage of total claims are summarized in Table 6.

Table 6

Denied Ostomy Supply Claims as a Percentage of Total Claims

Carrier	2012	2013
A	0.0%	0.0%
B	0.0%	0.0%
C	0.4%	0.2%
D	0.2%	0.2%
E	0.0%	0.0%

As shown in Table 6, denied ostomy supply claims represent an insignificant amount when compared to total claims.

Mercer’s internal database shows that ostomy supplies represented about 0.02 percent of all allowable costs as well as paid claims for the three year period 2010 – 2012, indicating that ostomy supplies do not represent a material portion of total claims.

³⁰ Department of Legislative Services, Maryland General Assembly, 2014 Session, Senate Bill 671, Fiscal and Policy Note, accessed April 17, 2014.

Mercer estimates the full cost of the proposed mandate to be \$0.07 per member per month. We define the marginal cost of a proposed mandate as the additional cost carriers will incur if required to provide coverage for a proposed mandate that they would not have provided otherwise. Table 7 summarizes the full and marginal costs of the proposed mandate.

Table 7

**Full and Marginal Cost Estimates for
Mandated Coverage of Ostomy Equipment and Supplies**

	Full Cost	Marginal Cost
Estimated cost as a % of average cost per group policy	0.02%	0.00%
Estimated cost as a % of average wage	0.00%	0.00%

Resources

Chasse, J. B. "Health Insurance – Coverage for Ostomy Equipment and Supplies – Required." Fiscal and Policy Note. Department of Legislative Services, Maryland General Assembly. 2014 Session.

Colin Cooke, Researcher, United Ostomy Associations of America. May 29, 2014.

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US Census Bureau: State and County QuickFacts. "Maryland Quick Facts from the US Census Bureau." Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Non-employer Statistics, Economic Census, Survey of Business Owners, Building Permits. Last revised March 27, 2014.