ORDER OF THE OFFICE OF THE COMMISSIONER OF INSURANCE CREATING A RULE

To create Ins 3.35, Wis. Adm. Code,

Relating to colorectal cancer screening coverage.

ANALYSIS PREPARED BY THE OFFICE OF THE COMMISSIONER OF INSURANCE (OCI)

1. **Statutes interpreted:**

   ss. 600.01, 628.34 (12), 632.895 (16m), Stats.

2. **Statutory authority:**

   ss. 600.01 (2), 601.41 (3), 601.42, 628.34 (12), 632.895 (16m), Stats.

3. **Explanation of OCI's authority to promulgate the proposed rule under these statutes:**

   2009 Wis. Act 346 created s. 632.895 (16m), Stats., and required the commissioner to promulgate rules that specify guidelines for the colorectal cancer screening that shall be covered, specify the factors for determining whether an individual is at high risk for colorectal cancer and to update periodically the guidelines as medically appropriate.

4. **Related statutes or rules:**

   None

5. **The plain language analysis and summary of the proposed rule:**

   The proposed rule implements s. 632.895 (16m), Stats., mandating coverage for colorectal cancer screening. For flexibility, the proposed rule allows insurers and self-insured health plans to select from among the U.S. Preventive Services Task Force, the National Cancer Institute, or the American Cancer Society guidelines it will follow related to colorectal cancer screening intervals and specific screening tests or procedures. Insurers and self-insured health plans are to inform enrollees of the guideline or guidelines they use and if they use more than one guideline, which guideline is primary if a dispute arises.

   The proposed rule requires insurers and self-funded health plans to provide coverage of at least three of four identified screening tools: fecal occult blood test,

flexible sigmoidoscopy, colonoscopy and computerized tomographic colonography. The determination for appropriate screening test or procedure is to be based upon medical necessity or medically appropriate basis and is eligible for internal and independent review.

Additionally, the proposed rule sets forth guidance on determination of persons at high risk for developing colorectal cancer. The proposed guidance is based upon the guidelines of the American Cancer Society as it is the only organization that has detailed standards for high risk categories and screening intervals. However, the rule does permit insurers to utilize additional criteria if the National Cancer Institute or the U.S. Preventive Service Task Force develops high risk criteria.

In light of federal health reform, the proposed rule requires insurers to comply with preventive services contained in the patient protection and affordable care act of 2010, PL 111-148, as amended by the federal health care and education reconciliation act of 2010, P.L. 111-152. Finally, insurers and self-insured health plans are required to annually review the selected guidelines and comply with updates in the subsequent policy year.

6. Summary of and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The patient protection and affordable care act of 2010, PL 111-148, as amended by the federal health care and education reconciliation act of 2010, P.L. 111-152, ("ACA"), includes colorectal cancer screening as a covered preventive health service contained in the 45 CFR Subtitle A §147.130. However, the federal requirements for preventive health are not effective until January 1, 2014. The federal regulation addresses cost sharing limitations that insurers may impose when the service is a preventive health service that supersede the state's law when implemented in 2014. The federal regulations and the ACA are not as specific as s. 632.895 (16m), Stats., and do not address high risk factors, therefore the state's law would not be preempted.

7. Comparison of similar rules in adjacent states as found by OCI:

Illinois: 215ILCS5/356x Sec. 356x. Mandate provides coverage for colorectal cancer examination and screening in accordance with the published American Cancer Society guidelines. Illinois law also permits consideration of other existing colorectal cancer screening guidelines issued by nationally recognized professional medical societies or federal government agencies, including the National Cancer Institute, the Centers for Disease Control and Prevention, and the American College of Gastroenterology. The Illinois mandate restricts insurers from imposing deductible, coinsurance, waiting period, or other cost-sharing limitations that is greater than that required for other coverage under the policy.

Iowa: No similar law.

Michigan: No similar law.

Minnesota: Minnesota statutes section 62A.30 mandates coverage for accident and health insurance, health maintenance organizations excluding fixed indemnity and accident only policies. Every policy or plan shall provide coverage of routine screening procedures for cancer and the office or facility visit. Among the cancer screenings listed colorectal cancer is included. Reference is made to include other proven ovarian cancer screening evaluated by the federal food and drug administration or the National Cancer Institute.

8. A summary of the factual data and analytical methodologies that OCI used in support of the proposed rule and how any related findings support the regulatory approach chosen for the proposed rule:

OCI surveyed insurers doing business in Wisconsin regarding coverage of screening tests and procedures for colorectal cancer and found that of the insurers surveyed, all insurers currently provide coverage for some form of colorectal cancer screening.

As to guidelines, OCI consulted with the department of health services, representatives and discussed the proposed rule with interested parties including the American Cancer Society, Wisconsin Radiological Society, Wisconsin Association of Health Plans and numerous providers. The guidelines utilized in the rule include not

only the American Cancer Society but also National Cancer Institute and the U. S. Preventive Services Task Force.

9. Any analysis and supporting documentation that OCI used in support of OCI's determination of the rule's effect on small businesses under s. 227.114:

There are no insurers that offer comprehensive health insurance that qualify as small businesses in accordance with s. 227.114 (1), Wis. Stat. Intermediaries that solicit individual health insurance will be required to use the new form but since it is available at no cost from the office, the effect will be minimal.

10. See the attached Private Sector Fiscal Analysis.

There will be no significant fiscal effect on the private sector as the proposed rules add a benefit for consumers with little additional cost since most if not all insurers and self-funded health plans currently provide coverage.

11. A description of the Effect on Small Business:

This rule will require intermediaries to learn about the colorectal cancer benefit but will not have a fiscal impact.

12. Agency contact person:

A copy of the full text of the proposed rule changes, analysis and fiscal estimate may be obtained from the Web site at: **http://oci.wi.gov/ocirules.htm**

or by contacting Inger Williams, OCI Services Section, at:

Phone: (608) 264-8110
Email: inger.williams@wisconsin.gov
Address: 125 South Webster St – 2nd Floor, Madison WI 53703-3474
Mail: PO Box 7873, Madison, WI 53707-7873

13. Place where comments are to be submitted and deadline for submission:

The deadline for submitting comments is 4:00 p.m. on the 14th day after the date for the hearing stated in the Notice of Hearing.

Mailing address:

Julie E. Walsh
Legal Unit - OCI Rule Comment for Rule Ins 335
Office of the Commissioner of Insurance
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Web site: **http://oci.wi.gov/ocirules.htm**

The proposed rule changes are:

SECTION 1. Ins 3.35 (title) is created to read:

Ins 3.35 (title) **Colorectal cancer screening coverage**.

Ins 3.35 **(1)** APPLICABILITY. (a) This section applies to disability insurance policies as defined at s. 632.895 (1) (a), Stats., unless otherwise excepted in s. 632.895 (16m) (c), Stats., that are issued or renewed on or after December 1, 2010. This section applies to Medicare supplement and cost plans but does not include limited –scope plans including vision and dental, hospital indemnity, income continuation, accident-only benefits, and long-term care policies. This section also applies to self-insured health plans as defined at s. 632.745 (24), Stats.

(b) For a disability insurance policy and a self-insured health plan covering employees who are affected by a collective bargaining agreement the coverage under this section first applies as follows:

1. If the collective bargaining agreement contains provisions consistent with s. 632.895 (16m), Stats., coverage under this section first applies the earliest of any of the following: the date the disability insurance policy is issued or renewed on or after December 1, 2010, or the date the self-insured health plan is established, modified, extended or renewed on or after December 1, 2010.

2. If the collective bargaining agreement contains provisions inconsistent with s. 632.895 (16m), Stats., the coverage under this section first applies on the date the health benefit plan is first issued or renewed or a self-insured health plan is first established, modified, extended, or renewed on or after the earlier of the date the collectively bargained agreement

expires, or the date the collectively bargained agreement is modified, extended or renewed on or after December 1, 2010.

(2) DEFINITIONS. In addition to the definitions contained in s. 632.895 (1), Stats., for purposes of this section all the following apply:

(a) "Designated guideline" means the recommendations of the U.S. Preventive Services Task Force, the National Cancer Institute, or the American Cancer Society regarding colorectal cancer screening guidelines identified by the insurer or self-insured health plan for compliance.

(b) "Enrollee" means an insured or enrollee of a health plan subject to s. 632.895 (16m), Stats.

(c) "Self-insured health plan" means a self-insured governmental health plan offered by the state, county, city, village, town, or school district that provides coverage of any diagnostic or surgical procedure.

(3) COLORECTAL CANCER SCREENING GUIDELINES AND UPDATES. (a) Insurers may utilize one or more of the most current colorectal cancer screening guidelines issued by the U.S. Preventive Services Task Force, the National Cancer Institute, or the American Cancer Society as the basis for the coverage offered for preventive colorectal cancer screening tests and procedures. If an insurer or self-insured health plan elects to designate more than one guideline, the insurer or self-insured health plan shall specify the guideline that will be primary in the event of a conflict between the designated guidelines. Insurers shall provide notice of the selected guideline or guidelines and which guideline is primary in a prominent location within the plan summary and in the notice provided to insureds when a benefit is denied based upon the primary guideline.

(b) Insurers and self-insured health plans shall at least annually review the designated guidelines and incorporate modifications to be effective the first day of the subsequent plan year.

(4) COVERED SCREENING. Insurers offering disability insurance and self-insured health plans shall offer as a covered benefit the screening for colorectal cancer that may be

subject to limitations, exclusions and cost-sharing provisions that generally apply under the plan and comply with all of the following:

(a) Insurers and self-insured health plans shall cover evidence-based, recommended preventive colorectal cancer screening tests or procedures contained in the most current version of the designated guideline.

(b) In accordance with the most current recommendations from the designated guideline for frequency of testing, insurers and self-insured health plans shall provide as a covered benefit, colorectal cancer screening tests or procedures for enrollees who are 50 years of age or older other than as provided for in sub. (5) (b). Medically appropriate or medically necessary covered screening tests or procedures shall at least include 3 of the following:

1. Fecal occult blood test.

2. Flexible sigmoidoscopy.

3. Colonoscopy.

4. Computerized tomographic colonography.

(c) Insurers and self-insured health plans may require the enrollee's health care provider or the enrollee's primary care provider to obtain prior authorization for screening tests or procedures when the screening test or procedure is not contained in the most current version of guideline recommendations designated by the insurer or self-insured health plan.

(d) Disputes regarding coverage of medically appropriate or medically necessary evidence-based screening tests or procedures are subject to internal grievance and independent review as provided by ch. Ins 18.

(5) FACTORS FOR HIGH RISK. (a) In accordance with recommended factors for identifying persons at high risk for colorectal cancer developed by the American Cancer Society, insurers and self-insured health plans shall provide as a covered benefit evidence-based colorectal cancer screening tests and procedures at recommended ages and intervals for enrollees determined to be at high risk for developing colorectal cancer. Insurers and self-

insured health plans that designated either the U.S. Preventive Services Task Force or the National Cancer Institute as the designated guideline may include additional high risk factors when the guidelines identify factors for persons at high risk for colorectal cancer. All insurers and self-insured health plans shall at a minimum consider all of the following factors, as appropriate, when determining whether an enrollee is at high risk for colorectal cancer:

1. Personal history of colorectal cancer, polyps or chronic inflammatory bowel disease.

2. Strong family history in a first-degree relative or two or more second-degree relatives of colorectal cancer or polyps.

3. Personal history or family history in a first or second-degree relative of hereditary colorectal cancer syndromes.

4. Other conditions, symptoms or diseases that are recognized as elevating one's risk for colorectal cancer as determined by the U.S. Preventive Services Task Force, the National Cancer Institute or the American Cancer Society.

(b) Notwithstanding sub. (4) (b), insurers and self-insured health plans shall provide as a covered benefit evidence-based, recommended colorectal cancer screening tests or procedures for high risk enrollees no later than the earliest recommended age determined to be medically appropriate or medically necessary.

(c) Disputes regarding an enrollee's status as being at high risk or factors to be considered as high risk for colon cancer are subject to internal grievance and independent review as provided by ch. Ins 18.

(6) PREVENTIVE SERVICES COMPLIANCE. Notwithstanding s. 632.895 (16m), Stats., insurers and self-insured health plans shall comply with P.L. 111-148 and 45 CFR Part 147.130 relating to cost-sharing provisions of preventive services including colon cancer screening.

SECTION 2. This section may be enforced under ss. 601.41, 601.64, 601.65, 628.10, Stats., or ch. 645, Stats., or any other enforcement provision of chs. 600 to 646, Stats.

SECTION 3. These changes will take effect on the first day of the month after publication, as provided in s. 227.22(2) (intro.), Stats.

Dated at Madison, Wisconsin, this 10th day of May, 2011.

Theodore K. Nickel
Commissioner of Insurance

Office of the Commissioner of Insurance
Private Sector Fiscal Analysis

For s. Ins 3.35 relating to colorectal cancer screening coverage and affecting small business

This rule change will have no significant effect on the private sector regulated by OCI.

FISCAL ESTIMATE WORKSHEET

Detailed Estimate of Annual Fiscal Effect

☒ ORIGINAL ☐ UPDATED		LRB Number	Amendment No. if Applicable
☐ CORRECTED ☐ SUPPLEMENTAL		Bill Number	Administrative Rule Number **INS 335**

Subject
colorectal cancer coverage and affecting small business

One-time Costs or Revenue Impacts for State and/or Local Government (do not include in annualized fiscal effect):
None

Annualized Costs:	**Annualized Fiscal impact on State funds from:**	
A. State Costs by Category	**Increased Costs**	**Decreased Costs**
State Operations - Salaries and Fringes	**$ 0**	**$ -0**
(FTE Position Changes)	(**0** FTE)	(**-0** FTE)
State Operations - Other Costs	**0**	**-0**
Local Assistance	**0**	**-0**
Aids to Individuals or Organizations	**0**	**-0**
TOTAL State Costs by Category	**$ 0**	**$ -0**
B. State Costs by Source of Funds	**Increased Costs**	**Decreased Costs**
GPR	**$ 0**	**$ -0**
FED	**0**	**-0**
PRO/PRS	**0**	**-0**
SEG/SEG-S	**0**	**-0**
C. State Revenues Complete this only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fee, etc.)	**Increased Rev.**	**Decreased Rev.**
GPR Taxes	**$ 0**	**$ -0**
GPR Earned	**0**	**-0**
FED	**0**	**-0**
PRO/PRS	**0**	**-0**
SEG/SEG-S	**0**	**-0**
TOTAL State Revenues	**$ 0 None**	**$ -0 None**

NET ANNUALIZED FISCAL IMPACT

	STATE	LOCAL
NET CHANGE IN COSTS	$ **None 0**	$ **None 0**
NET CHANGE IN REVENUES	$ **None 0**	$ **None 0**

Prepared by:	**Telephone No.**	**Agency**
Julie E. Walsh	(608) 264-8101	Insurance
Authorized Signature:	**Telephone No.**	**Date** (mm/dd/ccyy)

Division of Executive Budget and Finance
DOA-2048 (R10/2000)

Wisconsin Department of Administration

FISCAL ESTIMATE

☒ ORIGINAL ☐ UPDATED

☐ CORRECTED ☐ SUPPLEMENTAL

LRB Number	Amendment No. if Applicable
Bill Number	Administrative Rule Number **INS 335**

Subject

colorectal cancer coverage and affecting small business

Fiscal Effect

State: ☒ No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation.

☐ Increase Existing Appropriation ☐ Increase Existing Revenues
☐ Decrease Existing Appropriation ☐ Decrease Existing Revenues
☐ Create New Appropriation

☐ Increase Costs - May be possible to Absorb Within Agency's Budget ☐ Yes ☐ No

☐ Decrease Costs

Local: ☒ No local government costs

1. ☐ Increase Costs ☐ Permissive ☐ Mandatory
2. ☐ Decrease Costs ☐ Permissive ☐ Mandatory
3. ☐ Increase Revenues ☐ Permissive ☐ Mandatory
4. ☐ Decrease Revenues ☐ Permissive ☐ Mandatory
5. Types of Local Governmental Units Affected: ☐ Towns ☐ Villages ☐ Cities ☐ Counties ☐ Others _____ ☐ School Districts ☐ WTCS Districts

Fund Sources Affected ☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

Affected Chapter 20 Appropriations

Assumptions Used in Arriving at Fiscal Estimate

Long-Range Fiscal Implications

None

Prepared by:	**Telephone No.**	**Agency**
Julie E. Walsh	(608) 264-8101	Insurance
Authorized Signature:	**Telephone No.**	**Date** (mm/dd/ccyy)