

Clearinghouse Rule 10-150

STATE OF WISCONSIN

OFFICE OF THE COMMISSIONER OF INSURANCE (OCI)

★★★ NOTICE OF RULEMAKING HEARING ★★★

NOTICE IS HEREBY GIVEN that pursuant to the authority granted under s. 601.41(3), Stats., and the procedures set forth in under s. 227.18, and 227.24 (4), Stats., OCI will hold a public hearing to consider the adoption of the attached proposed rulemaking order and the emergency rule published November 29, 2010, affecting s. Ins 3.35, Wis. Adm. Code, relating to colorectal cancer screening coverage and affecting small business.

HEARING INFORMATION

Date: January 25, 2011

Time: 9:30 am, or as soon thereafter as the matter may be reached

Place: OCI, Room 227, 125 South Webster St 2nd Floor, Madison, WI

Written comments can be mailed to:

Julie E. Walsh
Legal Unit - OCI Rule Comment for Rule Ins 605
Office of the Commissioner of Insurance
PO Box 7873
Madison WI 53707-7873

Written comments can be hand delivered to:

Julie E. Walsh
Legal Unit - OCI Rule Comment for Rule Ins 605
Office of the Commissioner of Insurance
125 South Webster St – 2nd Floor
Madison WI 53703-3474

Comments can be emailed to:

Julie E. Walsh
julie.walsh@wisconsin.gov

Comments submitted through the Wisconsin Administrative Rule Web site at: <http://adminrules.wisconsin.gov> on the proposed rule will be considered.

The deadline for submitting comments is 4:00 p.m. on the 10th day after the date for the hearing stated in this Notice of Hearing.

SUMMARY OF PROPOSED RULE & FISCAL ESTIMATE

For a summary of the rule see the analysis contained in the attached proposed rulemaking order. There will be no state or local government fiscal effect. The full text of the proposed changes, a summary of the changes and the fiscal estimate are attached to this Notice of Hearing.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

Notice is hereby further given that pursuant to s. 227.114, Stats., the proposed rule may have an effect on small businesses. The initial regulatory flexibility analysis is as follows:

- a. Types of small businesses affected:
Insurance agents, LSHO, Town Mutuals, Small Insurers.
- b. Description of reporting and bookkeeping procedures required:
Adds the option of electronically filing forms to the OCI and requires attestation of the Flesch score and tool used to determine the Flesch score. No other bookkeeping or reporting requirements other than are currently required.
- c. Description of professional skills required:
Some small businesses, not otherwise exempted by rule, will need to update the website to include information on how to request or access the insured's policy. Other than creating the notice, no other professional skills other than are currently required.

OCI SMALL BUSINESS REGULATORY COORDINATOR

The OCI small business coordinator is Eileen Mallow and may be reached at phone number (608) 266-7843 or at email address eileen.mallow@wisconsin.gov

CONTACT PERSON

A copy of the full text of the proposed rule changes, analysis and fiscal estimate may be obtained from the OCI internet Web site at <http://oci.wi.gov/ocirules.htm> or by contacting Inger Williams, Public Information and Communications, OCI, at: inger.williams@wisconsin.gov, (608) 264-8110, 125 South Webster Street – 2nd Floor, Madison WI or PO Box 7873, Madison WI 53707-7873.

PROPOSED 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 and affecting small business.

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 must 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 governmental 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 governmental 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 governmental 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 governmental 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 supersedes 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 must 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 governmental 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
PO Box 7873
Madison WI 53707-7873

Street address:

Julie E. Walsh
Legal Unit - OCI Rule Comment for Rule Ins 335
Office of the Commissioner of Insurance
125 South Webster St – 2nd Floor
Madison WI 53703-3474

Email address:

Julie E. Walsh
julie.walsh@wisconsin.gov

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., including Medicare supplement and cost plans 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 governmental 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 governmental 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 governmental 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.

(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 governmental health plan for compliance.

(b) “Self-insured governmental 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. 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 governmental health plan elects to designate more than one guideline, the insurer or self-insured governmental 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.

(4) COVERED SCREENING. Insurers offering disability insurance and self-insured health plans must offer as a covered benefit the screening for colorectal cancer 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 must 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 except as provided for in sub. (5) (b). Covered screening tests or procedures shall at least include 3 of the following as determined to be medically appropriate or medically necessary:

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.

(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 must 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 governmental health plans must 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.

(6) PREVENTIVE SERVICES COMPLIANCE. Notwithstanding s. 632.895 (16m), Stats., insurers and self-insured governmental health plans must comply with P.L. 111-148 and 45 CFR Part 147 relating to cost-sharing provisions of preventive services including colon cancer screening.

(7) UPDATED GUIDELINES. Insurers and self-insured governmental health plans are required to comply with the most current colorectal cancer screening recommendations designated by the insurer and self-insured governmental health plan except as provided in sub. (4) (b) and (5). Insurers and self-insured governmental health plans shall at least annually review recommendations of the designated guideline and reflect the recommendations of most current version of the designated guideline as covered benefits for the subsequent policy year.

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 apply to policies issued or renewed on or after December 1, 2010.

Dated at Madison, Wisconsin, this ____ day of _____, 2010.

Sean Dilweg
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
 CORRECTED SUPPLEMENTAL

LRB Number	Amendment No. if Applicable
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:	
	Increased Costs	Decreased Costs
A. State Costs by Category		
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		
GPR	\$ 0	\$ -0
FED	0	-0
PRO/PRS	0	-0
SEG/SEG-S	0	-0
C. State Revenues <small>Complete this only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fee, etc.)</small>	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

	<u>STATE</u>		<u>LOCAL</u>
NET CHANGE IN COSTS	\$ <u>None 0</u>		\$ <u>None 0</u>
NET CHANGE IN REVENUES	\$ <u>None 0</u>		\$ <u>None 0</u>

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

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. <input type="checkbox"/> Increase Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	3. <input type="checkbox"/> Increase Revenues <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	5. Types of Local Governmental Units Affected: <input type="checkbox"/> Towns <input type="checkbox"/> Villages <input type="checkbox"/> Cities <input type="checkbox"/> Counties <input type="checkbox"/> Others _____
2. <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	4. <input type="checkbox"/> Decrease Revenues <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory	<input type="checkbox"/> School Districts <input type="checkbox"/> WTCS Districts

Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	Affected Chapter 20 Appropriations
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Assumptions Used in Arriving at Fiscal Estimate

Long-Range Fiscal Implications

None

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