State of Rhode Island and Providence Plantations
OFFICE OF THE HEALTH INSURANCE COMMISSIONER
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OFFICE OF THE HEALTH INSURANCE COMMISIONER REGULATION 14
TOBACCO CESSATION PROGRAMS

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Preamble

According to the Centers for Disease Control, smoking accounts for an estimated 438,000 deaths, or nearly 1 of every 5 deaths, each year in the United States. More deaths are caused each year by tobacco use than by all deaths from human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries, suicides, and murders combined.[1] In addition, the economic costs of smoking in the United States are estimated at $167 billion annually ($92 billion in productivity losses from premature death and $75.5 billion in health care expenditures).[2] State government can reduce tobacco use, save lives and reduce overall health care expenditures by improving accessibility to smoking cessation programs. This regulation sets out to (1) improve access to smoking cessation by establishing uniform standards for cessation treatment coverage, (2) redefine tobacco cessation treatments consistent with the most recent clinical practice guideline sponsored by United States Department of Health and Human Services and (3) improve transparency of tobacco cessation coverage for Rhode Island's insured population.

Under the initial version of the tobacco cessation benefit statutes, R. I. Gen Laws §§ 27-18-66,

[1] Centers for Disease Control and Prevention, "Smoking and Tobacco Use, Fact Sheet," *available at* www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/health_effects.htm (last viewed April 21, 2009).

[2] Centers for Disease Control and Prevention, "Cigarette Smoking Among Adults - United States, 2006," *Morbidity and Mortality Weekly Report*, November 9, 2007 / 56(44);1157-1161, available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5644a2.htm (last viewed Jan. 16, 2009).

27-19-57, 27-20-53 and 27-41-70,[3] health insurers in Rhode Island were required to provide coverage for nicotine replacement therapy (NRT) when combined with 8 half-hour tobacco cessation counseling sessions. NRT was the only medication for which coverage was expressly required. However, the statutes also gave the Office of the Health Insurance Commissioner (OHIC) the ability to define additional tobacco cessation treatments that insurers must cover. Based on this express statutory authority, OHIC developed the previous version of this regulation, which required health insurers to provide coverage for all FDA-approved medications when used either in combination with tobacco cessation counseling sessions, or as a stand-alone medication. The regulation was developed based on recommendations set out in a federally-sponsored, scientifically validated clinical practice guideline.[4]

Subsequent to the promulgation of this regulation, the tobacco cessation benefit statutes, R. I. Gen. Laws §§ 27-18-66, 27-19-57, 27-20-53 and 27-41-70,[5] were amended to redefine the mandatory coverage requirement for smoking cessation treatment. Under the new laws, smoking cessation treatment includes over-the-counter and prescription FDA-approved smoking cessation medications in cases where the medication is paired with 16 half-hour mandatory counseling sessions. In addition, the statute allows health insurers to limit annual coverage of these drugs to two courses of medication of up to fourteen weeks each. The statute does, however, authorize OHIC to redefine, through regulation, smoking cessation treatment for the purposes of the benefit mandate as long as it is done so in accordance with the most current clinical practice guideline sponsored by the United States Department of Health and Human Services (or its component agencies).

Through this amended regulation, OHIC redefines smoking cessation treatment for the purpose of R. I. Gen. Laws §§ 27-18-66, 27-19-57, 27-20-53 and 27-41-70 consistent with the most current clinical practice guideline sponsored by the United States Department of Health and Human Services, "Treating Tobacco Use and Dependence. A Clinical Practice Guideline."[6]

OHIC has taken this step because the revisions to R. I. Gen. Laws §§ 27-18-66, 27-19-57, 27-20-53 and 27-41-70 make substantial changes to the prior versions of the tobacco cessation mandate that are not supported by the clinical practice guideline. First, the revisions potentially limit coverage for FDA-approved smoking cessation medications by allowing insurers to restrict coverage to beneficiaries who participate in 16 half-hour counseling sessions. While the combination of counseling and mediations is generally recognized as providing the best chances of a successful quit-attempt, a requirement that someone attend 16 half-hour counseling sessions as a condition for coverage of FDA-approved anti-smoking medications does not appear to be medically justified and could present a significant barrier to coverage for those beneficiaries who cannot attend 16 counseling sessions.[7] Second, the guideline does not limit the number of

[3] P.L. 2006, ch. 262, § 1, eff. July 3, 2006; P.L. 2006, ch. 293, § 1, eff. July 3, 2006; P.L. 2008, ch. 475, § 81, eff. July 5, 2008.

[4] Fiore MC, Bailey WC, Cohen SJ, et al. Treating Tobacco Use and Dependence. A Clinical Practice Guideline. US Department of Health and Human Services. Public Health Service, 2008, available at www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.28163 (last visited November 20, 2009).

[5] P.L. 2009, ch. 187, §§ 1-5, eff. Nov. 4, 2009.

[6] Available at www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.28163 (last visited November 20, 2009).

[7] The mandatory pairing of medication with counseling sessions is contrary to the clinical practice guideline (in other words, it not a recommended treatment protocol). Indeed, such restrictions are opposed

courses of treatment that should be made available to someone who wants to quit smoking.

Section 1 Authority

This regulation is promulgated in accordance with R.I. Gen. Laws §§ 27-18-66, 27-19-57, 27-20-53, 27-41-70, 42-14-5, 42-14-17, and 42-14.5-1 *et seq*.

Section 2 Purpose

This regulation establishes consistent cessation treatment coverage across health insurance carriers, further defines tobacco cessation treatments to include treatments included in the most recent clinical practice guideline issued by the federal government, and promotes transparency of coverage to enhance access by insureds.

Section 3 Standards for Tobacco Cessation Programs

(a) Every individual or group health insurance contract, plan or policy delivered, issued for delivery or renewed in this state that provides medical coverage that includes coverage for physician services in a physician's office or that provides major medical or similar comprehensive-type coverage shall include coverage for smoking cessation treatment, provided that if such medical coverage does not include prescription drug coverage, such contract, plan or policy shall not be required to include coverage for nicotine replacement therapy or any prescription drugs. Such medical coverage will, however, be required to provide outpatient counseling benefits for smoking cessation.

(b) As used in this regulation, smoking cessation treatment includes the tobacco dependence treatments identified as effective in the most recent clinical practice guideline published by the United States Department of Health and Human Services for treating tobacco use and dependence.[8]

(c) Nicotine replacement therapy includes but is not limited to nicotine gum, patches, lozenges, nasal spray, and inhaler.

(d) Health insurance contracts, plans, or policies to which this regulation applies, may impose copayments and/or deductibles for smoking cessation treatment mandated by this section consistent with the contracts', plans' or policies' copayments and/or deductibles for physician services and medications. Nothing contained in this regulation shall impact the

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by the American Lung Association, the nation's foremost anti-smoking advocacy organization. In addition, while the revised statutes now allow an insurer to require a total 480 minutes of counseling as a condition for coverage of a medication, the guideline found that counseling that exceeds a total of 300 minutes (10 half-hour sessions) has diminishing value and, on average, actually results in lower abstinence rates than counseling sessions of shorter duration. In fact, the guideline notes, "there was a clear trend for abstinence rates to increase across contact time, up to the 90-minute mark. There was no evidence that more than 90 minutes of total contact time substantially increases abstinence rates.**"** It is also important to note that requiring 16 counseling sessions not only appears to be of little medical value, it may also create a cost-barrier for some people seeking treatment for their tobacco addiction. Since persons trying to quit may have to attend 16 counseling sessions to get coverage for their FDA-approved medication, they may also have to pay 16 separate copayments (one for each session) for the counseling. For some, this may make smoking cessation treatments cost-prohibitive.

[8] Fiore MC, Bailey WC, Cohen SJ, et al. Treating Tobacco Use and Dependence. A Clinical Practice Guideline. US Department of Health and Human Services. Public Health Service, 2008. Available at: http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf.

reimbursement, medical necessity or utilization review, managed care, or case management practices of these health insurance contracts, plans or policies.

(e) This section shall not apply to insurance coverage providing benefits for:

(1) Hospital confinement indemnity;

(2) Disability income;

(3) Accident only;

(4) Long-term care;

(5) Medicare supplement;

(6) Limited benefit health;

(7) Specified disease indemnity;

(8) Sickness or bodily injury or death by accident or both; and

(9) Other limited benefit policies.

Section 4 Reporting

(a) Each carrier that issues an individual or group health insurance contract, plan or policy subject to this regulation shall, no later than March 15 of each year, submit to the Director of the Department of Health a report describing the carrier's compliance with this regulation during the previous calendar year. Such report shall substantially conform to the model report established by the Department of Health and posted on the Department's website.

(b) Any carrier that fails to submit a report to the Department of Health as required by this regulation shall be subject to the administrative penalties provided for in R.I. Gen. Laws § 42-14-16.

Section 5 Severability

If any provision of this regulation or the application thereof to any person or circumstances is held invalid or unconstitutional, the invalidity or unconstitutionality shall not affect other provisions or applications of this regulation which can be given effect without the invalid or unconstitutional provision or application, and to this end the provisions of this regulation are severable.

Section 6 Effective Date

This regulation shall be effective as indicated below. EFFECTIVE DATE: August 14, 2009

AMENDED: January 27, 2010

AMENDED: January 1, 2011