

REGULAR

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2015-0428-03	REGULATORY ACTION NUMBER 2015-1215-03S	EMERGENCY NUMBER
For use by Office of Administrative Law (OAL) only			
NOTICE		REGULATIONS	

ENDORSED - FILED
In the office of the Secretary of State
of the State of California

JAN 25 2016

1:51 PM

2016 JAN 25 A 10:23
OFFICE OF
ADMINISTRATIVE LAW

AGENCY WITH RULEMAKING AUTHORITY
Board of Pharmacy

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE	
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON		TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn			NOTICE REGISTER NUMBER 2015, 19-2	PUBLICATION DATE 5/8/2015

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Nicotine Replacement Products	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT Section 1746.2
	AMEND
	REPEAL
TITLE(S) 16	

3. TYPE OF FILING

<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify) _____	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input checked="" type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify) _____
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input checked="" type="checkbox"/> State Fire Marshal <i>Medical Board</i>
<input checked="" type="checkbox"/> Other (Specify) Awet Kidane, Director, Department of Consumer Affairs		

7. CONTACT PERSON Lori Martinez	TELEPHONE NUMBER (916) 574-7917	FAX NUMBER (Optional) (916) 574-8618	E-MAIL ADDRESS (Optional) Lori.Martinez@dca.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Virginia Herold</i>	DATE 1/22/16
TYPED NAME AND TITLE OF SIGNATORY Virginia Herold, Executive Officer, Board of Pharmacy	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JAN 25 2016

Office of Administrative Law

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STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2015-04028-03 <i>per agency request</i>	REGULATORY ACTION NUMBER 2015-1215-035	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

2015 DEC 15 A 11:30
OFFICE OF ADMINISTRATIVE LAW

NOTICE

REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY
Board of Pharmacy

AGENCY FILE NUMBER (if any)

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OAL USE ONLY <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER 2015, 19-2	PUBLICATION DATE 5/8/2015

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Nicotine Replacement Products	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) N/A
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ACTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT Section 1746.2
	AMEND N/A
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<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify)	

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SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Virginia Herold</i>	DATE
TYPE, NAME AND TITLE OF SIGNATORY Virginia Herold, Executive Officer, Board of Pharmacy	

Board of Pharmacy
Department of Consumer Affairs

ORDER OF ADOPTION

Adopt §1746.2 of Article 5 of division 17 of Title 16 of the California Code of Regulations to read as follows:

§1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

(A) Review the patient's current tobacco use and past quit attempts.

(B) Ask the patient the following screening questions:

(i) Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)

(ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)

(iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)

(iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)

(v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

- (vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

- (C) When a nicotine replacement product is furnished:
- (i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
 - (ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., <http://smokefree.gov>), apps, and local cessation programs.
- (D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy's or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.



NICOTINE REPLACEMENT THERAPY MEDICATIONS FOR SMOKING CESSATION

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY						COMBINATION NRT
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	
Product	Nicorette ¹ , Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette Lozenge, ¹ Nicorette Mini Lozenge, ¹ Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CQ ¹ , Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS ² Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution	Nicotrol Inhaler ² Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Combinations with demonstrated efficacy Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
Precautions	<ul style="list-style-type: none"> ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy³ and breastfeeding ▪ Adolescents (<18 years) 	<ul style="list-style-type: none"> ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy³ and breastfeeding ▪ Adolescents (<18 years) 	<ul style="list-style-type: none"> ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy³ (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years) 	<ul style="list-style-type: none"> ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy³ (category D) and breastfeeding ▪ Adolescents (<18 years) 	<ul style="list-style-type: none"> ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy³ (category D) and breastfeeding ▪ Adolescents (<18 years) 	<ul style="list-style-type: none"> ▪ See precautions for individual agents
Dosing	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette > 30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks 	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette > 30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks 	<p><u>> 10 cigarettes/day:</u> 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><u>≤ 10 cigarettes/day:</u> 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> ▪ Maximum <ul style="list-style-type: none"> – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months 	<p>6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but “puff” as if fighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months 	<p><u>Reserve for patients smoking ≥ 10 cigarettes/day.</u></p> <p>Long-acting NRT: to prevent onset of severe withdrawal symptoms</p> <ul style="list-style-type: none"> ▪ Nicotine patch 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks <p style="text-align: center;">PLUS</p> <p>Short-acting NRT: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco</p> <ul style="list-style-type: none"> ▪ Nicotine gum (2 mg) 1 piece q 1–2 hours as needed <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> ▪ Nicotine lozenge (2 mg) 1 lozenge q 1–2 hours as needed <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> ▪ Nicotine nasal spray 1 spray in each nostril q 1–2 hours as needed <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> ▪ Nicotine inhaler 1 cartridge q 1–2 hours as needed

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY						COMBINATION NRT
GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER		
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> - Lightheadedness - Nausea/vomiting - Throat and mouth irritation 	<ul style="list-style-type: none"> ▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia 	<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ See adverse effects listed for individual agents
ADVANTAGES	<ul style="list-style-type: none"> ▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others ▪ Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours 	<ul style="list-style-type: none"> ▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
DISADVANTAGES	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments ($\leq 60^{\circ}\text{F}$) 	<ul style="list-style-type: none"> ▪ Combination therapy is more costly than monotherapy ▪ See disadvantages listed for individual agents

¹ Marketed by GlaxoSmithKline.

² Marketed by Pfizer.

³ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

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