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In the Pharmacy: Pharmacists Furnishing Nicotine Replacement Products

Learning Objectives:

- Review the California State Board of Pharmacy regulations for pharmacists to furnish nicotine replacement therapy (NRT) products, which have been in effect since January 2016.
- Describe strategies to promote smoking cessation in pharmacy practice.
- Summarize best practices for responsible prescribing of NRT products.

Key Points:

- Tobacco dependence continues to be a leading cause of preventable morbidity and mortality, and often requires repeated interventions and multiple quit attempts.
- Medicaid enrollees have a high and relatively unchanging smoking prevalence, in comparison to the non-Medicaid population.
- NRT, including combinations of NRT formulations (for example, patch plus a short-acting NRT as needed), is a recommended first line treatment. Currently, nicotine gum, lozenge, and patch are on the Medi-Cal fee-for-service Contract Drugs List.
- Managed Care Plans (MCPs) are contractually required to cover all FDA-approved tobacco cessation medications for adults who use tobacco products. At least one FDA-approved tobacco cessation medication must be available without authorization.
- Effective January 25, 2016, pursuant to Section 1746.2 of the *California Code of Regulations*, pharmacists are authorized to furnish nicotine replacement products approved by the U.S. Food and Drug Administration (FDA) for use by prescription in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California.
- While the regulation allowing pharmacists in California to furnish NRT became effective over two years ago, claims data for the Medi-Cal fee-for-service program shows limited adoption among California pharmacists.
- Recent legislation allows pharmacist reimbursement for specified pharmacy services, including furnishing of NRT products. For claims to be reimbursed, the furnishing pharmacist must complete the *Medi-Cal Ordering/Referring/Prescribing Provider Application/Agreement/Disclosure Statement For Physician and Non-physician Practitioners* (DHCS 6219) application form and be enrolled as an ordering, referring, and prescribing (ORP) provider. DHCS 6219 application forms are available on the Medi-Cal website.

Background
Tobacco dependence continues to be a leading cause of preventable morbidity and mortality. Each year, smoking kills approximately 480,000 Americans and costs the nation more than $300 billion a year, including nearly $170 billion in direct medical care for adults and $156 billion in lost productivity.[1,2] Notably, Medicaid enrollees have a high and relatively unchanging smoking prevalence compared to the general population, and smoking-related disease is thus a major contributor to increasing Medicaid costs.[3,4] According to California Health Interview Survey data available through the UCLA Center for Health Policy Research, the estimated smoking prevalence among adult Medi-Cal beneficiaries in 2016 was 16.0% (versus 11.2% statewide).[5]

Tobacco use and exposure to secondhand smoke are known causes of cardiovascular disease, respiratory disease, multiple cancers, reproductive complications, and many other diseases.[1] A majority of tobacco users are aware of these health consequences and are interested in quitting. In fact, 68% of current smokers in the United States report they want to quit completely; however, less than 10% succeed on their first attempt.[6] Tobacco dependence is a chronic disease that often requires repeated interventions and multiple quit attempts.[7] Clinicians and health care systems can play a major role in helping patients develop an effective smoking cessation plan.

Current clinical guidelines emphasize the importance of both counseling and medication in assisting tobacco users with cessation efforts.[7] They also encourage health systems, insurers, and purchasers to make the following effective treatments available: individual, group, and telephone counseling and seven medications approved by the FDA (bupropion sustained-release, varenicline, and five NRT formulations: patch, gum, inhaler, nasal spray, and lozenge).[7] The 2001 – 2010 National Health Interview Survey noted that only 31.7% of patients had used counseling and/or medications when they tried to quit.[6]

Nicotine Replacement Therapy (NRT)
NRT aids in smoking cessation by delivering nicotine to reduce the severity of nicotine withdrawal symptoms. There is strong evidence supporting the effectiveness of NRT to treat tobacco dependence and aid in smoking cessation. Clinical trial data show all commercially available NRT formulations increase the odds of quitting approximately 1.5 to 2-fold, regardless of setting.[7,8] Furthermore, some data suggest that NRT combination therapy, which includes the patch once daily plus a short-acting NRT as needed, is more effective than single agent NRT.[8,9] The patch provides a consistent release of nicotine to prevent withdrawal symptoms and the short-acting NRT can be used as needed for situational or breakthrough cravings. Combination therapy might be especially helpful for smokers with a high nicotine dependency and those who have tried and failed monotherapy.

NRT formulations currently available on the Medi-Cal fee-for-service Contract Drugs List are listed in Table 1, along with dosage recommendations and instructions for use.[10-12] For all patients using NRT medications, individual, group, and/or telephone counseling should always be recommended as adjunctive therapy.[7]

Table 1. NRT Medications for Smoking Cessation Available on the Medi-Cal Fee-for-Service Contract Drugs List*

	NRT Formulations Used as Monotherapy			Combination NRT
	Patch	**Gum**	**Lozenge**	
Product	**NicoDerm CQ[10], Generic** 7 mg, 14 mg, 21mg (24-hour release)	**Nicorette[11]** 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette[12], Nicorette Mini[12]** 2 mg, 4 mg cherry, mint	**Combinations with demonstrated efficacy include:** Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge
Dosing	<u>*>10 cigarettes/day:*</u> 21 mg/day x 4 – 6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks <u>*≤10 cigarettes/day:*</u> 14 mg/day x 6 weeks 7 mg/day x 2 weeks • Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week • May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) • Duration: 8 – 10 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1 – 6: 1 piece q 1 – 2 hours Weeks 7 – 9: 1 piece q 2 – 4 hours Weeks 10 – 12: 1 piece q 4 – 8 hours • 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	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1 – 6: 1 lozenge q 1 – 2 hours Weeks 7 – 9: 1 lozenge q 2 – 4 hours Weeks 10 – 12: 1 lozenge q 4 – 8 hours • 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	<u>*Reserve for patients smoking ≥10 cigarettes/day:*</u> **Long-acting NRT**: to prevent onset of severe withdrawal symptoms **1. <u>Nicotine patch</u>** 21 mg/day x 4 – 6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks **PLUS** **Short-acting NRT**: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco **2. <u>Nicotine gum (2 mg)</u>** 1 piece q 1 – 2 hours as needed *OR* **3. <u>Nicotine lozenge (2 mg)</u>** 1 lozenge q 1 – 2 hours as needed

* As of the date of publication of this article, these drugs appear on the Medi-Cal fee-for-service Contract Drugs List, although some medications may have additional restrictions, including on manufacturer codes. For current information, use the online Medi-Cal Formulary search tool available on the Formulary File web page of the Department of Health Care Services (DHCS) website.

A Pharmacologic Product Guide of all FDA-approved medications for smoking cessation is available at the University of California, San Francisco Rx for Change website.

Of note, Medi-Cal Managed Care Plans (MCPs) are contractually required to cover all FDA-approved tobacco cessation medications for adults who use tobacco products. At least one FDA-approved tobacco cessation medication must be available without authorization. See All Plan Letter 16-014 for additional details about NRT and other comprehensive tobacco prevention and cessation services for managed care beneficiaries.

California Pharmacists Can Furnish NRT for Smoking Cessation
In order to provide timely access to nicotine replacement products and to ensure patients receive information to appropriately initiate smoking cessation medication therapy, regulations allowing pharmacists to furnish NRT products became effective January 25, 2016. Section 4052.9(a) of the California *Business and Professions Code* authorizes a pharmacist to furnish NRT products approved by the FDA for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. The full §1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products can be found on the California State Board of Pharmacy website.

When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment initiates smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

1. Review the patient's current tobacco use and past quit attempts.
2. Ask the patient the following screening questions, which are available in several languages on the California State Board of Pharmacy website:
   - Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
   - Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
   - 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)
   - 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)
   - Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)
   - Have you been diagnosed with temporomandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

3. When a nicotine replacement product is furnished:
   - The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
   - 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 (like Smokefree.gov), apps, and local cessation programs.
4. The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

Prior to furnishing prescription nicotine replacement products, pharmacists must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, such as the Furnishing Nicotine Replacement Therapy: Smoking Cessation Training Program for Pharmacists, an online course offered through the California Pharmacists Association (CPhA) website, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy. Additionally, pharmacists must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

Finally, pharmacists must notify the patient's primary care provider of any NRT product furnished to the patient and must document any NRT product furnished in the patient's medication record within the originating pharmacy or health care facility.

NRT Furnished by Pharmacists in the Medi-Cal Fee-for-Service Population

A retrospective cohort study was conducted to assess the prevalence of pharmacist furnishing of NRT products within the Medi-Cal fee-for-service population. Paid pharmacy claims for all NRT products were reviewed with a date of service between March 1, 2016, and November 30, 2017. There were no additional inclusion or exclusion criteria. The prescriber National Provider Identifier (NPI) for each paid claim was reviewed in order to determine if the prescriber was a pharmacist or pharmacy. County-level practice location data were reviewed for all pharmacist-furnished paid claims. Paid claims for NRT products per beneficiary were calculated for this same timeframe (March 1, 2016, through November 30, 2017). March 1, 2016, was chosen as the starting point for the analysis because the California State Board of Pharmacy NRT protocol was not publicized until February 3, 2016, in a press release.

During this 21-month period, a total of 21,763 paid claims for NRT products were processed for 11,813 Medi-Cal fee-for-service beneficiaries. The majority of those beneficiaries used the nicotine patch (n = 20,478; 94%). As shown in Table 2, only 260 (1%) paid claims for NRT products were furnished by pharmacists to a total of 103 Medi-Cal fee-for-service beneficiaries.

Table 2. Paid Claims for NRT in the Medi-Cal Fee-for-Service Population, by Formulation, between March 1, 2016, and November 30, 2017.

Formulation	Pharmacist-Furnished n (%)	All Paid Claims n (%)
Nicotine Patch	168 (65%)	20,478 (94%)
Nicotine Gum	31 (12%)	892 (4%)
Nicotine Lozenge or Mini Lozenge	61 (23%)	393 (2%)

While use of gum and lozenges was much lower overall in comparison to the patch, utilization was slightly higher among pharmacist-furnished paid claims. This may be due in part to a much higher rate of combination NRT among pharmacist-furnished paid claims (24% vs. 3%). In fact, while less than 1% of Medi-Cal fee-for-service beneficiaries with a paid claim for an NRT product were pharmacist-furnished, these beneficiaries (n = 25) made up 6% of the total Medi-Cal fee-for-service beneficiaries (n = 430) with paid claims for combination NRT.

Of note, paid claims for pharmacy-furnished NRT to Medi-Cal fee-for-service beneficiaries came from only 27 pharmacists in California during this time period, with the vast majority of paid claims (n = 188; 72%) coming from San Francisco County. Finally, within San Francisco County, almost all of the claims (n = 157; 84%) came from one location: the San Francisco Department of Public Health (SFDPH).

A closer look at the pharmacy claims data also shows differences among those claims from SFDPH, where 100% of beneficiaries were provided with combination NRT and the average number of paid NRT claims per beneficiary was 4.8, in comparison to an overall rate of 1.8 paid NRT claims. These data suggest that beneficiaries who are furnished NRT products from SFDPH completed the recommended duration of treatment.

Discussion/Conclusion

While the regulation allowing pharmacists in California to furnish NRT became effective over two years ago, there has not yet been widespread adoption in the Medi-Cal fee-for-service program. A follow-up evaluation that includes Medi-Cal managed care beneficiaries would be valuable to determine the overall adoption rate within the Medi-Cal program. Educational outreach efforts, including academic detailing, may help to understand the barriers to adoption, as well as the facilitators present in pharmacy practices successful at furnishing NRT.[13] Future research in this area becomes even more critical, as the data show pharmacist-furnished NRT was more likely to be combination NRT therapy, which has been shown to be more effective than single agent NRT.

Future adoption rates may also be impacted by recent legislation that allows pharmacist reimbursement as providers. Assembly Bill 1114, Chapter 602, Statutes of 2016 added *Welfare and Institutions Code*, Section 14132.968, which specifies the following pharmacy services as a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare & Medicaid Services:

a) Furnishing travel medications;

b) Furnishing naloxone hydrochloride;

c) Furnishing self-administered hormonal contraception;

d) Initiating and administering immunizations; and,

e) Providing tobacco cessation counseling and furnishing NRT.

For claims to be reimbursed, the furnishing pharmacist must complete the DHCS 6219 application form and be enrolled as an ordering, referring, and prescribing (ORP) provider. DHCS 6219 application forms are available on the Medi-Cal website.

General Clinical Recommendations:

- Evidence shows that even a brief intervention (less than 10 minutes) by health care providers can make a difference in tobacco quit rates. The "5 A's" can be an effective tool to guide the intervention (Table 3).[7]

Table 3. The 5 A's[7]

Ask about tobacco use	Identify and document tobacco use status for every patient at every visit.
Advise to quit	In a clear, strong, and personalized manner, urge every tobacco user to quit.
Assess willingness to make a quit attempt	Is the tobacco user willing to make a quit attempt at this time?
Assist in quit attempt	For the patient willing to make a quit attempt, offer medication and provide or refer for counseling or additional treatment to help the patient quit. For patients unwilling to quit at the time, provide interventions designed to increase future quit attempts.
Arrange followup	For the patient willing to make a quit attempt, arrange for follow-up contacts, beginning within the first week after the quit date. For patients unwilling to make a quit attempt at the time, address tobacco dependence and willingness to quit at next clinic visit.

- For patients unwilling to quit, another brief intervention strategy is to help patients identify barriers to cessation known as the "5 R's" (Table 4).[7]

Table 4. The 5 R's[7]

Relevance	Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation, health concerns, age, gender, and other important patient characteristics.
Risks	Ask the patient to identify potential negative consequences of tobacco use. Suggest and highlight those that seem most relevant to the patient. Emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco will not eliminate these risks.
Rewards	Ask the patient to identify potential benefits of stopping tobacco use. Suggest and highlight those that seem most relevant to the patient.
Roadblocks	Ask the patient to identify barriers or impediments to quitting and provide treatment (problem solving, counseling, medication) that could address barriers.
Repetition	The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.

- When time or expertise do not allow for comprehensive smoking cessation counseling, pharmacists and pharmacy technicians can follow The Brief Tobacco Intervention (also known as the "2 A's & R"), which is available as a pocket card on the Centers for Disease Control and Prevention (CDC) website:
  - Ask about tobacco use: "Do you currently smoke or use other forms of tobacco?"
  - Advise the patient to quit: "Quitting tobacco is one of the best things you can do for your health. I strongly encourage you to quit. Are you interested in quitting?"
  - Refer the patient to resources, including NRT products.
- Encourage active tobacco users to quit at every encounter, as multiple attempts are often required to treat tobacco dependence.
- Furnish combination NRT therapy, which has been shown to be more effective at improving quit rates than NRT monotherapy.
- Recommend both counseling and medication to patients for best results, unless contraindicated or not indicated, such as with light smokers (individuals smoking less than 10 cigarettes daily).
- Refer patients to the California Smokers' Helpline at 1-800-NO-BUTTS, which includes free telephone counseling, text messaging, and online self-help resources available in multiple languages.
- Promote the Great American Smokeout, a social campaign by the American Cancer Society held every year on the third Thursday of November. All health care providers are encouraged to promote this event and assist patients with planning their quit date.

Pharmacy-Specific Recommendations:

- All pharmacists should review the §1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products and complete the necessary training in order to furnish NRT products, either through the Furnishing Nicotine Replacement Therapy: Smoking Cessation Training Program for Pharmacists, an online course offered through the CPhA website, or an equivalent curriculum-based training program.
- Pharmacists and pharmacy technicians should identify and document current and past tobacco use or other nicotine use as a routine part of patient care, including smokeless tobacco and electronic nicotine delivery systems (for example, e-cigarettes, e-hookahs).
  - Pharmacy technicians can be trained to ask about tobacco use when gathering patient information and to document smoking status in the pharmacy computer.
  - Pharmacy technicians can also advise patients about the benefits of quitting and refer interested patients to the pharmacist for additional counseling and selection of NRT products.
- The CDC's *Tips From Former Smokers*® (*Tips*®) campaign can be a conversation starter within the pharmacy. The campaign offers several pharmacy-specific resources and handouts for patients, available on the CDC website.

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