Medi-Cal Rx

Pharmacists Furnishing of Nicotine Replacement Therapy Products

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Learning Objectives

- Review the California State Board of Pharmacy regulations for pharmacists to furnish nicotine replacement therapy (NRT) products.
- Describe strategies to promote tobacco cessation in pharmacy practice.
- Summarize best practices for pharmacists to furnish NRT products.

Key Points

- Tobacco dependence continues to be a leading cause of preventable morbidity and mortality, often requiring multiple quit attempts.
- Medicaid enrollees have a significantly higher rate of tobacco use when compared with the non-Medicaid population.
- Since January 25, 2016, pharmacists have been authorized to furnish NRT products approved by the U.S. Food and Drug Administration (FDA) in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California.
- Combination NRT or varenicline are recommended as first line therapies for tobacco cessation. Currently, the California protocol authorizes pharmacists to furnish combination NRT but not varenicline. Combination NRT includes the use of a long-acting acting formulation daily (i.e., nicotine patch) and a short-acting NRT formulation as needed for cravings (e.g., gum or lozenge), which has been shown to be more effective than either formulation used alone.
- After regulations that allowed pharmacists to furnish NRT became effective in 2016, claims data among the Medi-Cal population found limited adoption among California pharmacists.
- All FDA-approved NRT products are available on the *Medi-Cal Rx Contract Drugs List* (CDL), including the nicotine gum, lozenge, patch, and nasal spray.
- In order to receive Medi-Cal reimbursement for furnishing of tobacco cessation products, pharmacists must be enrolled as an Ordering, Referring, and Prescribing (ORP) provider.

Background

Tobacco use continues to be the leading preventable cause of morbidity and mortality in the United States, with almost half a million deaths attributed to tobacco use each year.[1,2] Tobacco use and exposure to secondhand smoke are known causes of cardiovascular disease,

respiratory disease, cancers, reproductive complications, and many other diseases.[1] Additionally, the economic burden of using tobacco is significant and costs the nation more than $600 billion annually.[1,2] Notably, smoking prevalence among the Medi-Cal population is higher compared to the overall population in California, and smoking-related disease is thus a major driver of costs in the Medi-Cal program.[3] It has been estimated that decreasing smoking prevalence by 1% in the Medi-Cal population could reduce costs by $630 million in one year.[3]

While the number of people in the United States who smoke cigarettes has decreased since 2017, the use of e-cigarettes and other smokeless tobacco products has increased significantly in recent years. According to the Centers for Disease Control and Prevention (CDC) the number of people who exclusively smoked cigarettes decreased by nearly 7 million between 2017 and 2023, but the number of people who exclusively used e-cigarettes increased by more than 7 million during the same timeframe.[4]

The California Tobacco Prevention Program (CTPP) at the California Department of Public Health (CDPH) monitors tobacco use in California among adults and adolescents and reported that although fewer adults are smoking cigarettes than in prior years, vaping and e-cigarette use have increased.[5] In 2022, approximately 11% of adults in California reported using at least one tobacco product in the last 30 days, including over 1.8 million individuals smoking cigarettes and 1.4 million individuals vaping. Among the Medi-Cal population, approximately 15% of adults reported current use of tobacco products, compared with 11% state-wide.[5]

Tobacco dependence is a chronic disease that often requires repeated interventions and multiple quit attempts. In California, 60% of adults who currently smoke cigarettes reported they either intended to quit smoking or tried to quit smoking for at least one day in the past year.[5]

However, while most people who currently use tobacco report having the desire to quit, research has shown that only a small percentage are successful in quitting. A recent study of over 28 million adults in the U.S. found that approximately two-thirds (67%) of adults who use tobacco wanted to quit smoking, approximately half (53.3%) tried to quit in the past year, but fewer than 1 in 10 (8.8%) successfully quit.[6] The study also found only half of individuals who saw a provider received assistance or advice to quit smoking.[6] Among individuals who made a quit attempt, less than 40% used any evidence-based treatment (counseling or medication), and only 5.3% used both medication and counseling to help them quit, highlighting the opportunity for providers to assist with tobacco cessation efforts.[6]

Providers and health care systems can play a major role in helping patients develop an effective quit plan. Current clinical guidelines emphasize the importance of both counseling and medication in assisting tobacco users with cessation efforts.[2,7,8] They also encourage health systems, insurers, and purchasers to make the following effective treatments available: individual, group, and telephone counseling and the medications approved by the FDA (sustained-release bupropion, varenicline, and NRT formulations: patch, gum, nasal spray, and lozenge).[2,7]

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.[2] Data have shown that NRT combination therapy, which includes the nicotine patch daily with a short-acting NRT product as needed for cravings, is more effective than using one NRT agent alone.[2,7] Combining a short-acting with a long-acting NRT product provides relatively constant levels of nicotine and the ability for acute dose titration as needed for withdrawal symptoms.[4] When initiating combination NRT, providers should determine the correct patch dosage depending on the number of cigarettes smoked per day.[2,9] The nicotine gum or lozenge strength is based on the time-to-first cigarette of the day.[10,11] It is generally recommended for individuals to use 1 piece every 1 to 2 hours as needed, and at least 9 pieces every day if used alone.[2] If combining the patch with the nasal spray, one spray should be administered to each nostril every 1 to 2 hours as needed.[2,12]

The *Clinical Practice Guideline* and the 2021 United States Preventive Task Force Recommendations on Tobacco Cessation recommend that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety.[7,8] Behavioral counseling interventions that exceed minimal advice to quit should be offered to pregnant people who are quitting smoking.[7,8] Providers should refer to the tobacco cessation guidance from the American College of Obstetricians and Gynecologists (ACOG) before prescribing tobacco cessation medications during pregnancy.

NRT formulations currently available on the CDL are listed in **Table 1** along with dosing recommendations (package inserts for patch, gum, lozenge and nasal spray). For all patients using NRT medications, individual, group, and/or telephone counseling should always be recommended as adjunctive therapy. [2,8] A Pharmacologic Product Guide of all FDA-approved medications for tobacco cessation is available on the University of California, San Francisco Rx for Change website.

Table 1. Strengths and Dosing Recommendations for NRT Medications Available on the *Medi-Cal Rx Contract Drugs List*

Nicotine Replacement Therapy (NRT) Products				
	Patch	**Gum**	**Lozenge**	**Nasal Spray**
Strengths	**OTC** 7 mg, 14 mg, 21 mg (24-hr release)	**OTC** 2 mg, 4 mg	**OTC** 2 mg, 4 mg	**Rx** 10 mg/ml nicotine solution; 0.5 mg nicotine/spray
Dosing Recommendations	**>10 cigarettes/day:** • 21 mg/day x 4-6 weeks • 14 mg/day x 2 weeks • 7 mg/day x 2 weeks **≤10 cigarettes/day:** • 14 mg/day x 6 weeks • 7 mg/day x 2 weeks **Duration:** 8-10 weeks	**First cigarette ≤30 min after waking:** 4 mg **First cigarette >30 min after waking:** 2 mg <u>Weeks 1-6:</u> • 1 piece every 1-2 hrs * <u>Weeks 7-9:</u> • 1 piece every 2-4 hrs * <u>Weeks 10-12:</u> • 1 piece every 4-8 hrs * **Maximum:** 24 pieces/day • If using as monotherapy, use at least 9 pieces/day for the first 6 weeks **Duration:** Up to 12 weeks	**First cigarette ≤30 min after waking:** 4 mg **First cigarette >30 min after waking:** 2 mg <u>Weeks 1-6:</u> • 1 lozenge every 1-2 hrs * <u>Weeks 7-9:</u> • 1 lozenge every 2-4 hrs * <u>Weeks 10-12:</u> • 1 lozenge every 4-8 hrs * **Maximum:** 20 lozenges/day • If using as monotherapy, use at least 9 lozenges/day for the first 6 weeks **Duration:** Up to 12 weeks	**1-2 doses/hr * (8-40 doses/day)** • 1 dose = 2 sprays (1 spray in each nostril) **Maximum:** • 5 doses/hour • 40 doses/day • If using as monotherapy, use at least 8 doses/day during the first 6-8 weeks • Gradually reduce daily dose over the next 4-6 weeks **Duration:** 12 weeks

* Refers to waking hours.

For current information on covered products, refer to the Contract Drugs & Covered Products Lists page on the Medi-Cal Rx Web Portal.

California Pharmacists Can Furnish NRT for Tobacco Cessation

Since January 2016, California pharmacists have been authorized to furnish NRT products approved by the FDA in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California.

This protocol outlines steps that pharmacists must complete when a patient requests or when a pharmacist decides to initiate tobacco cessation and treatment, including screening questions to identify higher-risk patients and possible allergies or contraindications. Prior to furnishing nicotine replacement products, pharmacists must have completed a minimum of two hours of an approved continuing education program specific to tobacco 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. The full §1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products can be found on the California State Board of Pharmacy website.

Additionally, pharmacists must complete ongoing continuing education (CE) focused on tobacco cessation therapy from an approved provider once every two years. Several web-based CE programs are available for free from the Rx for Change website that fulfill this requirement:

- Pharmacists' Prescribing for Tobacco Cessation Medications (2.0 hours)
- Rx for Change: Clinician-Assisted Tobacco Cessation (4.0 hours)
- Tobacco Cessation – Behavioral Counseling & Pharmacotherapy (2.5 hours)

Pharmacists can also refer to the Pharmacists Furnishing NRT for Smoking Cessation Provider Fact Sheet from Kick It California for helpful tips and answers to frequently asked questions about furnishing NRT.

NRT Furnished by Pharmacists in the Medi-Cal Population

A retrospective cohort study was conducted to assess the prevalence of pharmacist furnishing of NRT products within the Medi-Cal population. Paid pharmacy claims for all NRT products were reviewed with a date of service between January 1, 2024, and December 31, 2024. 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 member were calculated for this same timeframe.

A total of 335,092 paid claims for NRT products were processed for 98,255 Medi-Cal members during 2024. The majority (81%) of those members used the nicotine patch (n = 79,515), with 18% of members (17,896) using combination NRT (patch plus any short-acting NRT).

Only 4,716 (1%) paid claims for NRT products were furnished by pharmacists to a total of 1,374 (1%) Medi-Cal members. While the overall percentage of pharmacy-furnished paid claims has only increased by 0.2% since this analysis was first conducted using Medi-Cal fee-for-service (FFS) claims data from 2016 and 2017, the percentage of pharmacists furnishing

the more effective combination NRT almost doubled during this same time period, going from 24% of members receiving combination NRT to 47%.

Discussion/Conclusion

While the regulation allowing pharmacists in California to furnish NRT became effective in 2016, there has not yet been widespread adoption in 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. Future research in this area becomes even more critical, as the data show that pharmacist-furnished NRT was more likely to be combination NRT therapy (47% vs. 18%), which has been shown to be more effective than single-agent NRT.

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.
- For patients unwilling to quit, another brief intervention strategy is to help patients identify barriers to cessation known as the "5 R's."
- When time or expertise does not allow for comprehensive smoking cessation counseling, pharmacists and pharmacy technicians can follow The Brief Tobacco Intervention (also known as the "Ask-Advise-Refer"), which is available as a pocket card on the CDC website.
- Encourage active tobacco users to quit at every encounter, as multiple attempts are often required to treat tobacco dependence.
- Recommend 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 Kick It California (KIC), formerly known as the California Smokers' Helpline or 1-800-NO-BUTTS, which provides free telephone counseling, text messaging, and online self-help resources available in multiple languages for quitting smoking and vaping. Patients can call KIC at 1-800-300-8086 or visit the KIC website to enroll in the text message-based quit programs.
- 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 a CE program, such as those offered through Rx for Change, 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, vapes).
  - Pharmacy technicians can be trained to ask about tobacco use when gathering patient information and to document smoking status in the pharmacy system.
  - 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® 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.
- Additional resources for pharmacists can be found at the following websites:
  - The Quit Smoking Pharmacies website provides information about tobacco treatment services provided by community pharmacies, including a tool that allows patients to find pharmacies that provide tobacco cessation services in their area.
  - The Rx for Change website contains an Implementation Toolkit with resources for clinicians, patient education, as well as tools for pharmacies to facilitate implementation of pharmacist-furnishing of NRT.

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