Adult Oral Sedation in California: What Can a Dentist Do Without a Special Permit or Certificate From the Dental Board of California?

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ABSTRACT

A significant percentage of patients are fearful of dental procedures, and this has not changed significantly over the past 50 years. Apprehensive patients tend to avoid necessary dental treatment, and their quality of life is compromised in the long term. This article discusses the use of zaleplon, triazolam, and lorazepam to provide oral sedation for apprehensive adult dental patients. Patient evaluation, pharmacology, and selection based on duration of the dental procedure are discussed. Dentists can use the practical protocols and sample prescriptions provided in this article without obtaining special permits or certificates from the Dental Board.

Anxiety toward dental therapy has not changed significantly over the past 50 years, and various publications show that about 30 percent to 50 percent of patients are at least somewhat fearful of dental procedures.[1-5] Oral sedation, with appropriate doses of sedatives, can help reduce local anesthetic failures and decrease anxiety in a large percent of dental patients.[6,7] Oral premedication might be the sedative technique of choice for dentists because it is cost-effective, usually efficacious, requires minimal monitoring when correct doses are used, and is unlikely to result in complications.[8]

In 2006, Assembly Bill 1386 went into effect and added restrictions to the use of oral conscious sedation for adult patients. This bill was due to recommendations of a California Blue Ribbon Committee on Dental Anesthesia that was formed by the Dental Board of

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California. This independent committee represented the "communities of interest" on dental anesthesia in California (**Table 1**). The committee reviewed anesthesia trends in dentistry and presented the Dental Board with its recommendations.[9] The committee found that a significant number of dentists were attempting to produce conscious sedation in adults with oral medications. In order to protect the public's safety, the panel felt dentists who wanted to provide conscious sedation should have additional education on oral medications and sedation, and be required to have specific monitoring and emergency equipment in their offices. However, for the vast majority of dentists, the ability to prescribe adult oral sedative premedication remains unchanged.

The new law does not restrict dentists from prescribing sedatives in an attempt to produce anxiolysis. Anxiolysis is defined by the American Dental Association as the diminution or elimination of anxiety.[10] Anxiolysis is also defined as minimal sedation on the continuum of depth of sedation according to the American Society of Anesthesiologist (**Table 2**).[11] AB 1386 states, "Oral conscious sedation does not include dosages less than or equal to the single maximum recommended dose that can be prescribed for home use." Generally, these maximum doses can be found in references such as the package inserts, pharmaceutical Web sites, articles in dental literature, and yearly updated books such as the Physicians Desk Reference or USPDI.

The use of oral sedation premedication is both an art and a science. It is wise for each dentist to become familiar with only a small number of oral sedative regimens. In this way, one has a better chance of accurately predicting the correct dose for each patient, and understanding the precautions and side effects of each agent. Although there are a large number of sedatives that can be prescribed, recent dental articles have concentrated on the use of oral zaleplon, oral triazolam, and oral lorazepam.[5,7,12-16] The remainder of this article discusses guidelines and protocols for the use of these three medications.

Zaleplon is a short-acting hypnotic in the pyrazolopyrimidine class.[17] The onset of action of zaleplon is usually within 30 minutes, and it is rapidly eliminated with a half-life of approximately one hour. Zaleplon is a relatively new agent and there are relatively few articles on its use in dentistry. Both triazolam and lorazepam are benzodiazepam medications, and the main difference is in the effective time of sedation. The duration of action of triazolam is two to four hours compared to four to eight hours for lorazepam[5,13] (**Table 3**). General protocols for oral sedation with these medications are described in **Table 4**. It is important that the dentist review the patient medical and dental history to make sure there are no contraindications to these medications, and obtain informed consent prior to the oral premedication appointment. The patient must understand they will need a responsible adult to escort them when they take sedative medication. Suggested patient pretreatment instructions are presented in **Table 5**. Patients who are not reliable at following directions are not good candidates for oral sedative premedication.

This article provides guidelines for the anxiolytic doses for these medications, but these recommendations should not substitute for good clinical judgment and direct patient assessment. Patient factors such as liver enzyme induction, extremes of age, and tolerance because of past drug use may cause alterations in the proposed protocol. Precautions and drug interactions are presented in **Tables 6, 7, and 8**. If the calculated amount of medication is ineffective, the dentist can choose to terminate the dental appointment or continue if the patient is willing. If the patient's anxiety is not sufficiently diminished, the dentist must follow all normal dismissal procedures including releasing the patient to a responsible companion since the sedative may impair motor activity even when not relieving dental anxiety. A failure to produce anxiolysis may require a

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Table 1

CALIFORNIA BLUE RIBBON PANEL ON DENTAL ANESTHESIA

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Chair

Michael E. Cadra, DMD, MD
California Association of Oral and Maxillofacial Surgeons

Gary H. Chan, DDS
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California Society of Periodontists

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California Society of Pediatric Dentists

Stanley R. Surabian, DDS, JD
California Dental Association

Larry Trapp, DDS, MS
California Society of Dentist Anesthesiologists

Bruce Valentine, DDS
California Dental Association

Table 2

CONTINUUM OF DEPTH OF SEDATION DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA*

(Approved by American Society of Anesthesiologists House of Delegates on Oct. 13, 1999, and amended on Oct. 27, 2004)

	Minimal sedation (anxiolysis)	Moderate sedation/ analgesia ("conscious sedation")	Deep sedation/ analgesia	General anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal sedation (anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate sedation/analgesia ("conscious sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep sedation/analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering moderate sedation/analgesia ("conscious sedation") should be able to rescue*** patients who enter a state of deep sedation/analgesia, while those administering deep sedation/analgesia should be able to rescue*** patients who enter a state of general anesthesia.

* Monitored anesthesia care does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

***Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia, and hypotension) and returns the patient to the originally intended level of sedation.

Table 3

COMPARISON OF ZALEPLON, TRIAZOLAM, AND LORAZEPAM

	Zaleplon	Triazolam	Lorazepam
Available dosages	5 and 10 mg capsules	0.125 and 0.25 mg tablets	0.5, 1, and 2 mg tablets
Onset of hypnotic effect	15 to 30 minutes	30 minutes	30 to 60 minutes
Peak plasma concentration	1 hour	2 hours	1 to 6 hours
Duration of action	1 hour	2 to 4 hours	4 to 8 hours
Mean half-life	1 hour	2.3 hours	12 hours

Table 4

SUGGESTED PROTOCOL FOR THE USE OF ADULT ORAL SEDATIVE PREMEDICATION FOR ANXIOUS OR FEARFUL DENTAL PATIENTS

1. The dentist needs to determine the extent of dental treatment, evaluate the patient's medical history, research potential drug interactions, consult with the patient's physician, if appropriate, and obtain informed consent.

2. The patient must have a responsible adult companion for travel to and from the dental office. The patient must be escorted by this companion to and from the parking lot to prevent the patient from stumbling.

3. Patients take the prescribed medication according to directions and are instructed to have a light meal such as toast and beverage without caffeine.

4. Patients who have received oral sedatives are monitored visually and never left alone.

5. After the treatment is completed, postoperative directions are given to both the patient and companion, and the patient is released into the care of their companion for travel home. The companion is informed that the patient may have psychomotor and cognitive impairment for the rest of the day.

Table 5

SUGGESTED PATIENT PRETREATMENT INSTRUCTIONS

1. The sedative _____ (name of medication) is being prescribed to help reduce your anxiety before and during a dental procedure.

2. The medication may make you sleepy and impair your thinking and coordination. You must have a responsible adult companion for travel to and from the dental office.

3. You must be escorted by this companion to and from the parking lot to prevent you from stumbling.

4. You should take the prescribed medication according to directions, and you can have a light meal (no fat) such as toast without butter or margarine and beverage without caffeine. No grapefruit juice.

5. After the treatment is complete, a reliable companion must escort you out of the office and take you home. The sedative effects may linger for the rest of the day so you should have a responsible adult stay until you are able to take care of yourself.

Table 6

ZALEPLON PRECAUTIONS AND DRUG INTERACTIONS

Note this is a relatively new drug, and there are many potential drug interactions that have not been studied.

Relative and absolute contraindications:

Pregnancy, liver impairment, severe renal disease, respiratory disease, mental depression, children

Drug interactions that may increase effects:

Imipramine, thioridazine, cimetidine, erythromycin, ketoconazole, other central nervous system depressants

Drug interactions that may decrease effect:

Hepatic cytochrome P450 enzyme inducers such as carbamazepine, phenobarbital, phenytoin, rifampin

Foods that may increase effect:

Alcohol, valerian, kava, gotu kola

Foods that may decrease effect:

St. John's wort, caffeine. A high-fat/heavy meal can reduce the peak blood levels by 35 percent and the time to peak plasma levels by two hours.

Table 7

TRIAZOLAM PRECAUTIONS AND DRUG INTERACTIONS

Relative and absolute contraindications:

Acute narrow angle glaucoma, uncorrected open angle glaucoma, myasthenia gravis, respiratory diseases including severe sleep apnea and severe chronic obstructive pulmonary disease, pregnancy, lactation, severe liver impairment, renal impairment, children, mental depression, hypersensitivity to this drug or other benzodiazepines

Drug interactions that may increase effect:

Other central nervous system depressants, isoniazid, oral contraceptives, ranitidine, CYP3A4 inhibitors such as macrolide antibiotics (erythromycin, clarithromycin), azole antifungals, doxycycline, some calcium channel blockers

Drug interactions that may decrease effect:

Theophylline, CYP3A4 inducers such as aminoglutethimide, carbamazepine, nafcillin, nevirapine, phenobarbital, phenytoin, and rifamycins

Foods that may increase effect:

Grapefruit juice, alcohol, kava, gotu kola, star fruit, melatonin, valerian, chamomile

Foods that may decrease effect:

St. John's wort, caffeine

Table 8

LORAZEPAM PRECAUTIONS AND DRUG INTERACTIONS

Relative and absolute contraindications:

Acute narrow angle glaucoma, uncorrected open angle glaucoma, myasthenia gravis, respiratory diseases including severe sleep apnea and severe chronic obstructive pulmonary disease, pregnancy, lactation, severe liver impairment, renal impairment, children, mental depression, hypersensitivity to this drug or other benzodiazepines

Drug interactions that may increase effect:

Other central nervous system depressants, probenecid (used for gout).

Drugs that inhibit the oxidative metabolism of triazolam are less likely to affect lorazepam which undergoes direct glucuronide conjugation (Table 7).

Drug interactions that may decrease effect:

Theophylline. Drugs that induce the oxidative metabolism of triazolam are less likely to affect lorazepam that undergoes direct glucuronide conjugation (Table 7).

Foods that may increase effect:

Alcohol, valerian, St. John's wort, kava, gotu kola

Foods that may decrease effect:

Caffeine

Table 9

TOTAL ZALEPLON ANXIOLYTIC DOSING GUIDELINES

Weight (lb)	Age 41-64
<100	5 mg
150	10 mg
200+	10-15 mg

Elderly and debilitated patients are more sensitive to hypnotics, and the recommended dose for these patients is 5 mg. Doses over 10 mg in elderly and debilitated patients are not recommended. The maximum dose in the package insert is 20 mg for sleep.[17]

Table 10

TOTAL TRIAZOLAM ANXIOLYTIC DOSING GUIDELINES

Weight (lb)	Age 41-64
<100	0.250 mg
150	0.375 mg
200+	0.500 mg

Dose for debilitated or elderly patients should be reduced by 50 percent. Doses for healthy adults younger than 40 can be increased by 25 percent. With sublingual administration, systemic availability is approximately 27 percent higher compared with the same dose taken by the conventional oral route. The maximum single dose listed in the package insert is 0.5 mg for sleep.[18]

Adapted from Goodchild and Donaldson.[13]

Table 11

TOTAL LORAZEPAM ANXIOLYTIC DOSING GUIDE

Weight (lb)	Age 41-64
<100	1.0 mg
150	1.5 mg
200+	2.0 mg

Dose for debilitated or elderly patients should be reduced by 30 percent to 50 percent. Doses for healthy adults younger than 40 can be increased by 25 percent. The maximum single dose listed in the package insert is 4.0 mg for anxiety.[20]

Adapted from Goodchild and Donaldson.[13]

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change in future prescriptions, using the services of a dental anesthesiologist in the office, or referral to an office that provides conscious sedation or general anesthesia.

Goodchild and Donaldson reviewed the dental literature and recommended a maximum anxiolytic dose for triazolam of 0.625 mg, and a maximum dose of 2.5 mg for lorazepam.[13] Anxiolytic dosing guidelines are presented in **Tables 9, 10, and 11**. However, maximum and average doses are not appropriate for all patients, so it is necessary to adjust doses based on weight, age, health status, other medications the patient is taking, and previous patient experience with sedatives. The literature shows that age-related changes can impair benzodiazepine metabolism, and the maximum anxiolytic dose for elderly patients should be reduced by 50 percent for triazolam and 30 percent to 50 percent for lorazepam.[18-20] The opposite is true for younger adult patients (under 40 years) who may need a 25 percent increase in their weight-related anxiolytic dose. Sample prescriptions for morning and afternoon appointments are presented in **Tables 12, 13, and 14**.

When using a very short-acting agent such as zaleplon, there is a risk that recovery of psychomotor functions may take longer than one hour after the onset of action. Also, when taking triazolam with anxiolytic doses generally higher than the hypnotic dose, there is a risk that full recovery to a normal state of consciousness cannot always be anticipated at the completion of a four-hour procedure. Ganzberg found that 28.5 percent of the zaleplon-sedated patients and 78.5 percent of the triazolam-sedated patients felt that the sedative drugs lingered for the rest of the day.[12]

Consequently, zaleplon and triazolam patients must be accompanied by a responsible adult and not resume normal

Table 12

SAMPLE ZALEPLON PRESCRIPTIONS

Zaleplon comes in strengths of 5 mg and 10 mg

I. Morning and afternoon appointments

Patients are instructed to reduce the number of tablets they take in the morning if they feel sedate when they wake up in the morning.

Rx #1

Patient characteristics:
Age 45
Weight 160 lbs.
Health is good

Rx Zaleplon 5 mg
Disp Tabs #4
Sig Take two tablets at bedtime the night before dental procedure, and come 45 minutes early to your dental appointment and take two tablets in the office. This is for sedation, and you need to be accompanied by a responsible companion. Do not drive.

Rx #2

Patient characteristics:
Age 68
Weight 160 lbs.
Health is good

Rx Zaleplon 5 mg
Tabs #2
Sig Take one tablet at bedtime the night before dental procedure, and come 45 minutes early to your dental appointment and take the one tablet in the office. This is for sedation, and you need to be accompanied by a responsible companion. Do not drive.

activities for the remainder of the day. When using the short-acting sedatives, the opposite problem can also occur. The dentist must make sure there are no delays or interruptions or the sedation can wear off before the treatment is completed. When procedures tend to be longer than two hours, lorazepam has worked well for prolonged sedation.

To reiterate, this article is not intended to be a comprehensive review of all anxiolytic medications available. Examples of drugs for different length procedures based on the dental and medical literature were discussed. For example, diazepam has been recommended for dental anxiety in several references, but the author discussed triazolam and lorazepam.[22-24] Diazepam has a duration of action of six to eight hours, but it also has a primary half-life of 20 to 80 hours and 40 to 120 hour half-life for active secondary metabolites. In addition, two head-to-head comparisons of diazepam and triazolam found triazolam to be a more effective anxiolytic agent.[25,26]

For many patients, needed dental procedures are delayed or avoided due to anxiety, and quality of life is compromised in the long term. This article has attempted to provide practical oral sedation premedication protocols. Hopefully, this information will help dentists treat slightly and moderately apprehensive patients without the requirement of state conscious-sedation permits or certificates. ■■■■

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Table 13

SAMPLE TRIAZOLAM PRESCRIPTIONS

Triazolam comes in strengths of 0.125 mg and 0.25 mg

I. Morning appointments

Patients are instructed to reduce the number of tablets they take in the morning if they feel sedate when they wake up in the morning.

Rx #1

Patient characteristics:
Age 45
Weight 160 lbs.
Health is good
Appointment in the morning

Rx Triazolam 0.125 mg
Disp Tabs #4
Sig Take two tablets at bedtime the night before dental procedure and two tablets one hour before dental procedure. This is for sedation, and you need to be accompanied by a responsible companion. Do not drive.

Rx #2

Patient characteristics:
Age 68
Weight 160 lbs.
Health is good
Appointment in the morning

Rx Triazolam 0.125 mg
Tabs #2
Sig Take one tablet at bedtime the night before dental procedure and one tablet one hour before dental procedure. This is for sedation, and you need to be accompanied by a responsible companion. Do not drive.

II. Afternoon appointments

Rx#3

Patient characteristics
Age 45
Weight 160 lbs.
Health is good
Appointment is in the afternoon

Rx Triazolam 0.25 mg
Tabs #1
Sig One hour before your dental appointment, place tablet under tongue and do not swallow for at least two minutes to allow tablet to dissolve. This is for sedation, and you need to be accompanied by a responsible companion. Do not drive.

Rx #4

Patient characteristics
Age 68
Weight 160 lbs.
Health is good
Appointment in the afternoon

Rx Triazolam 0.125 mg
Tabs #1
Sig One hour before dental treatment, place tablet under tongue and do not swallow for at least two minutes to allow tablet to dissolve. This is for sedation, and you need to be accompanied by a responsible companion. Do not drive.

Table 14

SAMPLE LORAZEPAM PRESCRIPTIONS

Lorazepam comes in strengths of 0.5 mg, 1.0 mg, and 2.0 mgs

I. Morning appointments

Patients are instructed to reduce the number of tablets they take in the morning if they feel sedate when they wake up in the morning.

Rx #1

Patient characteristics:
Age 45
Weight 160 lbs.
Health is good
Appointment in the morning
Rx Lorazepam 0.5 mg
Tabs #5
Sig Take two tablets at bedtime the night before dental procedure and three tablets two hours before dental procedure. This is for sedation, and you need to be accompanied by a responsible companion when you come to the office. Do not drive.

Rx #2

Patient characteristics:
Age 68
Weight 160 lbs.
Health is good
Appointment in the morning
Rx Lorazepam 0.5 mg
Tabs #3
Sig Take one tablet at bedtime the night before dental procedure and two tablets two hours before dental procedure. This is for sedation, and you need to be accompanied by a responsible companion when you come to the office. Do not drive.

II. Afternoon appointments

Rx#3

Patient characteristics
Age 45
Weight 160 lbs.
Health is good
Appointment is in the afternoon
Rx Lorazepam 0.5 mg
Tabs #3
Sig Take three tablets two hours before dental procedure. This is for sedation, and you need to be accompanied by a responsible companion when you come to the office. Do not drive.

Rx #4

Patient characteristics
Age 68
Weight 160 lbs.
Health is good
Appointment in the afternoon
Rx Lorazepam 0.5 mg
Tabs #2
Sig Take two tablets two hours before dental procedure. This is for sedation, and you need to be accompanied by a responsible companion when you come to the office. Do not drive.

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