

COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2020 Sunset Review

The Application of Interim Therapeutic Restoration and Silver Diamine Fluoride by Dental Hygienists



October 15, 2020



Regulatory Reform

October 15, 2020

Members of the Colorado General Assembly c/o the Office of Legislative Legal Services State Capitol Building Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Pursuant to section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) at the Department of Regulatory Agencies (DORA) undertakes a robust review process culminating in the release of multiple reports each year on October 15.

A national leader in regulatory reform, COPRRR takes the vision of their office, DORA and more broadly of our state government seriously. Specifically, COPRRR contributes to the strong economic landscape in Colorado by ensuring that we have thoughtful, efficient and inclusive regulations that reduce barriers to entry into various professions and that open doors of opportunity for all Coloradans.

As part of this year's review, COPRRR has completed an evaluation of the application of interim therapeutic restoration and silver diamine fluoride by dental hygienists. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2021 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Sections 128 and 129, Article 220 of Title 12, C.R.S. The report also discusses the effectiveness of the Colorado Dental Board in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes for the review and discussion of the General Assembly.

To learn more about the sunset review process, among COPRRR's other functions, visit coprrr.colorado.gov.

Sincerely,

Patty Salazar **Executive Director**



Sunset Review: The Application of Interim Therapeutic Restoration and Silver Diamine Fluoride by Dental Hygienists

Background

What is regulated?

In Colorado, dental hygienists may apply interim therapeutic restoration (ITR) upon receiving a permit authorized by the Board, and may apply silver diamine fluoride (SDF) upon completion of additional educational requirements. ITR is a technique in which a dental hygienist may use hand instruments to remove portions of tooth decay, and a glass ionomer sealant is applied to adhere to the enamel of the tooth structure to prevent additional decay. SDF is an FDA-approved, topical treatment which halts the progression of decay and may prevent further decay in the affected tooth following application.

Why is it regulated?

Although the risks associated with the application of either procedure are low, both ITR and SDF have minimal risk of harm. When applying ITR, improper diagnosis or application of the restoration could cause damage to the tooth structure, and SDF can cause permanent staining or darkening of the decayed portion of the tooth. However, SDF does not cause staining if applied on healthy teeth or portions of a tooth that do not have decay.

Who is regulated?

There are currently 85 dental hygienists with Colorado addresses who have received a permit authorizing them to perform ITR. No permitting process is required for dental hygienists to perform SDF, and the number of dental hygienists who provide SDF is not available.

How is it regulated?

Dental hygienists must demonstrate the completion of specific requirements, including having a license in good standing, completing required coursework, and completing the required hours of supervised and/or unsupervised dental hygiene practice in order to receive a permit from the Board to apply ITR. Dental

hygienists may apply SDF after the completion of a course that must be at least one hour in length and consist of live and interactive instruction.

What does it cost?

During fiscal years 14-15 through 18-19, no program expenditures were reported and no full-time equivalent employees were dedicated to specifically oversee these two scope of practice elements.

Key Recommendations

- Continue the regulation of the application of ITR by dental hygienists.
- Continue the regulation of the application of SDF by dental hygienists.
- Combine future sunset reviews of both ITR and SDF with the sunset review of the Dental Practice Act.
- Amend sections 12-220-128(4)(c) and 12-220-129(2)(b), C.R.S., regarding the utilization of "store and forward transfer" technology to allow for the use of synchronous technologies in telehealth applications relating to ITR and SDF.
- Require all dentists collaborating in ITR
 procedures under telehealth to hold a
 Colorado license in good standing, and
 have either a physical practice location in
 Colorado, or in a surrounding state within
 a reasonable travel time considering the
 point of location of the treatment, for
 follow-up care.

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Background

Sunset Criteria

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria¹ and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are guided by statutory criteria and sunset reports are organized so that a reader may consider these criteria while reading. While not all criteria are applicable to all sunset reviews, the various sections of a sunset report generally call attention to the relevant criteria. For example,

- In order to address the first criterion and determine whether a particular regulatory program is necessary to protect the public, it is necessary to understand the details of the profession or industry at issue. The Profile section of a sunset report typically describes the profession or industry at issue and addresses the current environment, which may include economic data, to aid in this analysis.
- To ascertain a second aspect of the first sunset criterion--whether conditions
 that led to initial regulation have changed--the History of Regulation section of
 a sunset report explores any relevant changes that have occurred over time in
 the regulatory environment. The remainder of the Legal Framework section
 addresses the third sunset criterion by summarizing the organic statute and rules
 of the program, as well as relevant federal, state and local laws to aid in the
 exploration of whether the program's operations are impeded or enhanced by
 existing statutes or rules.
- The Program Description section of a sunset report addresses several of the sunset criteria, including those inquiring whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures and practices; whether the agency performs efficiently and effectively and whether the board, if applicable, represents the public interest.
- The Analysis and Recommendations section of a sunset report, while generally
 applying multiple criteria, is specifically designed in response to the tenth
 criterion, which asks whether administrative or statutory changes are necessary
 to improve agency operations to enhance the public interest.

¹ Criteria may be found at § 24-34-104, C.R.S.

These are but a few examples of how the various sections of a sunset report provide the information and, where appropriate, analysis required by the sunset criteria. Just as not all criteria are applicable to every sunset review, not all criteria are specifically highlighted as they are applied throughout a sunset review. While not necessarily exhaustive, the table below indicates where these criteria are applied in this sunset report.

Sunset Criteria	Where Applied
(I) Whether regulation by the agency is necessary to protect the public health, safety, and welfare; whether the conditions that led to the initial regulation have changed; and whether other conditions have arisen that would warrant more, less, or the same degree of regulation;	 Profile of the Profession. Legal Framework: History of Regulation. Recommendations 1 and 2.
(II) If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether agency rules enhance the public interest and are within the scope of legislative intent;	 Legal Framework: Legal Summary. Recommendations 5, 6, 7, 8, 9, 10, and 11.
(III) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters;	 Legal Framework: Legal Summary. Program Description and Administration. Recommendations 8 and 10.
(IV)Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;	 Program Description and Administration.
(V) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;	Program Description and Administration.
(VI) The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;	Profile of the Profession.Recommendation 9.
(VII) Whether complaint, investigation, and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;	Complaint and Disciplinary Activity.Fining Activity.
(VIII) Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel and whether entry requirements encourage affirmative action;	 Recommendation 5, 8, 10, and 11. Administrative Recommendation 1.

(IX) Whether the agency through its licensing or certification		
process imposes any sanctions or disqualifications on applicants		
based on past criminal history and, if so, whether the sanctions or		
disqualifications serve public safety or commercial or consumer		
protection interests. To assist in considering this factor, the analysis		
prepared pursuant to subsection (5)(a) of this section must include		
data on the number of licenses or certifications that the agency		
denied based on the applicant's criminal history, the number of		
conditional licenses or certifications issued based upon the		
applicant's criminal history, and the number of licenses or		
certifications revoked or suspended based on an individual's criminal		
conduct. For each set of data, the analysis must include the criminal		
offenses that led to the sanction or disqualification.		
I		

• Collateral Consequences: Criminal Convictions.

(X) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

• Recommendations 3, 4, 6, 7, and 9.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR's website at: coprrrr.colorado.gov.

The authority for dental hygienists to apply interim therapeutic restoration (ITR) and silver diamine fluoride (SDF), as enumerated in Sections 128 and 129 of Article 220, Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2021, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the application of ITR and SDF pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed authorities should be continued and to evaluate the performance of the Colorado Dental Board (Board) and the Division of Professions and Occupations (Division). During this review, the Board must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff attended Board meetings; interviewed Division staff, practitioners, officials with state and national professional associations and other stakeholders; and reviewed Colorado statutes and rules, and the laws of other states.

The major contacts made during this review include but are not limited to:

- Caring for Colorado Foundation;
- Colorado Dental Association;

- Colorado Dental Board;
- Colorado Dental Hygienists Association;
- Colorado Department of Health Care Policy and Financing;
- Colorado Health Foundation;
- Community College of Denver;
- Concord University;
- Dental Aid;
- Dentists Professional Liability Trust of Colorado;
- Division of Professions and Occupations, Department of Regulatory Agencies;
- Mountain Family Health Centers;
- Salud Family Health Centers;
- SMILES Dental Project;
- Summit Community Care Clinic; and
- University of Colorado at Denver.

Profile of the Profession

In a sunset review, COPRRR is guided by the sunset criteria located in section 24-34-104(6)(b), C.R.S. The criterion asks whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation.

In order to understand the need for regulation, it is first necessary to understand what the profession does, where they work, who they serve and any necessary qualifications.

Dental hygienists perform examinations to detect signs of oral disease, provide preventative care treatments, and offer general oral health education to patients. Dental hygienists perform many routine tasks, including:²

- Applying sealants;
- Removing tartar and plaque;
- Performing X-rays;
- Documenting treatment plans and patient care; and
- Providing patient education regarding oral hygiene techniques, such as proper brushing and flossing.

In addition, dental hygienists may work with a variety of tools including ultrasonic, hand, and power tools to complete their work. Utilizing power tools, dental hygienists may polish teeth, and may also remove stains with air-polishing devices.

² Bureau of Labor Statistics. *Occupational Outlook Handbook: What Dental Hygienists Do.* Retrieved April 8, 2020, from https://www.bls.gov/ooh/healthcare/dental-hygienists.htm#tab-2

The allowable tasks performed by dental hygienists vary from state to state, and may include various levels of supervision by dentists.³ In the United States, all 50 states require licensure for practice of the profession.⁴

In order to become a dental hygienist, an associate's degree is typically required, with the average length to completion of three years through a combination of classroom, laboratory, and clinical instruction. Dental hygienists can also obtain a bachelor's degree, and occasionally may complete a master's degree.⁵

In Colorado, dental hygienists can perform a variety of functions independently, such as the removal of stains and deposits by hand, the utilization of ultrasonic, or other approved devices. ⁶ In addition, dental hygienists may prescribe, administer, and dispense a variety of non-systemic agents, including, but not limited to, fluoride and antimicrobial agents for mouth rinsing. ⁷

Moreover, dental hygienists may apply interim therapeutic restoration (ITR) upon receiving a permit authorized by the Board, and may apply silver diamine fluoride (SDF) upon completion of additional educational requirements. These two tasks are the subject of this sunset report.

ITR is a technique in which a dental hygienist may use hand instruments to remove portions of tooth decay, and a glass ionomer sealant is applied to adhere to the enamel of the tooth structure to prevent additional decay.

SDF was approved by the Food and Drug Administration (FDA) in 2014 for use as a desensitizing agent, and may prevent further tooth decay painlessly without anesthesia. A known adverse effect of SDF is that it may permanently darken the tooth to which it is applied. However, SDF does not stain healthy tooth enamel.⁸

The sixth sunset criterion requires COPRRR to evaluate the economic impact of regulation. One way this may be accomplished is to review the expected salary of the profession.

In 2019, there were approximately 226,400 dental hygienists practicing in the United States with an annual mean wage of \$76,220 per year. There are currently 3,832 dental hygienists licensed in the state of Colorado with a current Colorado address.

⁸ Association of State and Territorial Dental Directors (ASTDD), *Silver Diamine Fluoride (SDF) Fact Sheet*, March, 2017.

³ Bureau of Labor Statistics. *Occupational Outlook Handbook: What Dental Hygienists Do.* Retrieved April 8, 2020, from https://www.bls.gov/ooh/healthcare/dental-hygienists.htm#tab-2

⁴ Bureau of Labor Statistics. *Occupational Outlook Handbook: How to Become a Dental Hygienist*. Retrieved April 8, 2020, from https://www.bls.gov/ooh/healthcare/dental-hygienists.htm#tab-4

⁵ Bureau of Labor Statistics. *Occupational Outlook Handbook: How to Become a Dental Hygienist*. Retrieved April 8, 2020, from https://www.https://www.bls.gov/ooh/healthcare/dental-hygienists.htm#tab-4 6 § 12-220-122(1)(a), C.R.S.

⁷ § 12-220-122(1)(g)(I), C.R.S.

⁹ Bureau of Labor Statistics. *Occupational Outlook Handbook: Dental Hygienists*, *Summary*. Retrieved July 31, 2020, from https://www.bls.gov/ooh/healthcare/dental-hygienists.htm

ITR and SDF procedures are performed by dental hygienists who work for or with both private dental providers and federally qualified health centers.

In Colorado, private dental providers who performed ITR were paid \$609.36 by Medicaid in fiscal year 18-19, and \$0 in fiscal year 19-20, as no ITRs were performed by private dental providers that year. During fiscal year 19-20, the reimbursement rate was \$50.78 per treatment.

Additionally, private dental providers who applied SDF were paid \$978.81 by Medicaid in fiscal year 18-19, and \$4,302.34 in fiscal year 19-20. During fiscal year 19-20, the reimbursement rate was \$5.53 per SDF treatment.

Federally qualified health centers (community-based centers that receive funds from the federal Health Resources and Services Administration's Health Center Program) provide both SDF and ITR treatments to patients. However, due to the nature of bundled billing for federally qualified health centers, data are not readily available regarding total payout amounts for each procedure type.

Reimbursement rates for both private providers and federally qualified health centers have decreased by one percent due to legislative requirements finalized in the 2020 Long Bill, effective as of July 1, 2020.

Legal Framework

History of Regulation

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first sunset criterion questions whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen that would warrant more, less or the same degree of regulation.

One way that COPRRR addresses this is by examining why the program was established and how it has evolved over time.

The General Assembly created the five-member Colorado Dental Board (Board) in 1889, and established the requirement for licensure of dental hygienists in 1919. The General Assembly revised the composition of the Board several times over the years. These changes included the addition of hygienists to the Board.

In 1979, the statute was amended by the General Assembly to allow dental hygienists to practice without the personal direction of a dentist in a variety of settings.

In 2015, House Bill 15-1309 was enacted by the General Assembly, which authorized dental hygienists to place interim therapeutic restorations (ITR) under the indirect supervision of a dentist utilizing telehealth technology. The bill also established the Interim Therapeutic Restorations Advisory Committee (Advisory Committee) to develop standards and training requirements for dental hygienists who perform ITR.

The seven members of the Advisory Committee were jointly appointed by the Speaker of the House and President of the Senate until December 31, 2016, at which time the Advisory Committee was repealed.

In 2017, the General Assembly passed additional legislation ¹⁰ which clarified components of practicing unsupervised dental hygiene within the scope of practice, and further provided that the Board may promulgate rules relating to "permissible and appropriate emergency drugs and reversal agents" prescribed, administered, or dispensed by dental hygienists.

Finally, the General Assembly passed House Bill 18-1045 which expanded the scope of practice for dental hygienists to allow for the application of silver diamine fluoride (SDF) under the direct or indirect supervision of a collaborating dentist utilizing telehealth technology. The Board was also directed to promulgate rules including further defining educational and other requirements, and the development of indications and limitations for the application of SDF by dental hygienists.

¹⁰ House Bill 17-1010.

During the 2019 legislative session, the General Assembly recodified Title 12, C.R.S. At that time, Article 35 was repealed and reenacted as Article 220. Though there were changes in the manner in which the law reads and many provisions of law were combined with common elements of other laws, none of those changes affected the implementation or enforcement of the Act.

Legal Summary

The second and third sunset criteria question:

Whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether agency rules enhance the public interest and are within the scope of legislative intent; and

Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters.

A summary of the current statutes and rules is necessary to understand whether regulation is set at the appropriate level and whether the current laws are impeding or enhancing the agency's ability to operate in the public interest.

As is specified in the Dental Practice Act (Act), the Board oversees regulation of dentists and dental hygienists, and consists of seven dentist members, three dental hygienist members, and three members of the public appointed by the Governor to serve four-year terms, for no more than two consecutive terms.¹¹

Each member of the Board is required to be a resident of the State of Colorado, and professional members must be currently licensed as a dentist or dental hygienist. Professional members must also have been actively engaged in clinical practice for at least five years prior to their appointment to the Board. 12

The Board promulgates rules for both dentists and dental hygienists, and may take actions including, but not limited to: 13

- Grant and issue licenses and renewal certificates;
- Grant temporary licenses;
- Conduct hearings to deny, suspend, or revoke a license or license renewal;
- Issue letters of admonition and confidential letters of concern;
- Impose administrative fines;

¹¹ § 12-220-105(1)(b), C.R.S.

¹² § 12-220-105(2), C.R.S.

¹³ § 12-220-106(1), C.R.S.

- Reprimand, censure, or place a licensee on probation if evidence of a violation of statutory provisions has occurred; and
- Conduct investigations and inspections related to compliance with the Act.

In Colorado, dental hygienists are regulated under the Act, located in sections 12-220-101 through 12-220-147, C.R.S.

Dental hygienists can perform a variety of functions independently, such as the removal of stains and deposits by hand or by the utilization of ultrasonic or other approved devices. In addition, dental hygienists may prescribe, administer, and dispense a variety of non-systemic agents, including but not limited to, fluoride and antimicrobial agents for mouth rinsing. ¹⁴

Additionally, section 12-220-123, C.R.S., highlights specific functions that may be performed by dental hygienists under the supervision of a licensed dentist, including:

- Preparation of casts,
- Administration of local anesthesia under the indirect supervision of a licensed dentist,
- Placement of interim therapeutic restorations, and
- Application of silver diamine fluoride.

Sections 12-220-128 and 12-220-129, C.R.S., the subjects of this review, regulate the two scope of practice elements regarding the placement of ITR and the application of SDF by dental hygienists.

Interim Therapeutic Restorations

Section 1.25 of the Colorado Dental Board rules provides additional clarification regarding the placement of ITR by dental hygienists.

A dental hygienist may perform ITR in order to stabilize the tooth for both adults and children until a licensed dentist has the opportunity to assess if further treatment is needed.¹⁵ This process may include:

- Utilization of hand instruments to remove soft tissue on the tooth, and
- Placement of glass ionomer as a restorative material.

Section 12-220-128, C.R.S., requires that in order for any dental hygienist to place an ITR in the State of Colorado, the dental hygienist must:¹⁶

Have a license in good standing to practice dental hygiene in Colorado;

¹⁴ § 12-220-122, C.R.S.

¹⁵ 3 CCR § 709-1-1.25 (A), Colorado Dental Board Rules and Regulations.

¹⁶ §§ 12-220-128(1) & (2), C.R.S.

- Complete a post-secondary course under the supervision of a member of faculty at an accredited Colorado dental or dental hygiene school;
- Carry professional liability insurance in an amount of not less than \$50,000 per claim and an aggregate liability for all claims during a calendar year of not less than \$300,000, unless eligible for a waiver of liability insurance. Coverage may also be maintained through the supervising dentist; ¹⁷ and
- Complete at least 2,000 hours of supervised, or 4,000 hours of unsupervised general dental hygiene practice after initial licensure, or a combination of hours as determined by the Board. The requirement to submit proof of hours of dental hygiene practice may be waived by the Board for a dental hygienist that performs ITR under the direct supervision of a dentist.

Additional statutory requirements regarding the placement of ITR by dental hygienists, include:

- Anesthesia shall not be used when placing an ITR by a dental hygienist;¹⁸
- A patient who receives treatment that was authorized by a dentist via telehealth communications must receive notice of their right to receive distance communication with the dentist upon their request; 19
- The patient or the patient's legal guardian must be informed in writing that the ITR procedure is a temporary repair, and that follow up with a dentist is necessary; and ²⁰
- Written notification to the patient or patient's representative is required when an ITR is performed by a dental hygienist when the procedure occurs at a location other than the dentist's practice location.²¹

Silver Diamine Fluoride

Following the completion of educational requirements, a dental hygienist may apply SDF under either the direct or indirect supervision of a dentist in a dental office setting.²² Supervision may also be performed via telehealth communications between the supervising dentist and the dental hygienist performing the procedure.²³ The supervising dentist is required to have a physical practice location within Colorado for any follow-up care.²⁴

In order for a dental hygienist in Colorado to be eligible to apply SDF, the dental hygienist must:²⁵

¹⁹ § 12-220-128(4)(c), C.R.S.

¹⁷ 3 CCR § 709-1-1.3-E-2-a, Colorado Dental Board Rules and Regulations.

¹⁸ § 12-220-128(3), C.R.S.

²⁰ § 12-220-128(7), C.R.S.

²¹ § 12-220-128(4)(b), C.R.S.

²² § 12-220-129(3), C.R.S.

²³ § 12-220-129(2)(b), C.R.S.

²⁴ 3 CCR § 709-1-1.26, Colorado Dental Board Rules and Regulations.

²⁵ § 12-220-129(1), C.R.S.

- Hold a license to practice in Colorado that is in good standing;
- Complete a postsecondary course that provides instruction regarding the limitations and use of SDF, and meets all other requirements established by the Board;
- Carry professional liability insurance in an amount of not less than \$50,000 per claim and an aggregate liability for all claims during a calendar year of not less than \$300,000, unless eligible for a waiver of liability insurance. Coverage may also be maintained through the supervising dentist; ²⁶ and
- Develop a collaborative agreement with the dentist that describes protocols, restrictions, limitations, and follow-up referral procedures, as well as any other requirements established by the Board.

The application of SDF must be provided in collaboration with a supervising dentist. If the treatment occurs at a location other than the dentist's practice, or if communication with the collaborating dentist occurs via telehealth, the dental hygienist must provide written notification to the patient or patient's representative that the treatment is provided in collaboration with a dentist.²⁷

²⁶ 3 CCR § 709-1-1.3-E-2-a, Colorado Dental Board Rules and Regulations.

²⁷ § 12-220-129(2)(a), C.R.S.

Program Description and Administration

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The third, fourth and fifth sunset criteria question:

Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures practices and any other circumstances, including budgetary, resource and personnel matters;

Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively; and

Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates.

In part, COPRRR utilizes this section of the report to evaluate the agency according to these criteria.

The Colorado Dental Board (Board), located within the Department of Regulatory Agencies' Division of Professions and Occupations (Division), oversees the regulation of dental hygienists in Colorado pursuant to the Dental Practice Act (Act).

Sections 12-220-128 and 12-220-129, C.R.S., parts of the Act, are the subject of this review. They regulate two scope of practice elements regarding the placement of interim therapeutic restoration (ITR) and the application of silver diamine fluoride (SDF) by dental hygienists.

The Board meets on at least a quarterly basis to perform duties relating to the administration of the Act including the issuance of licenses, the consideration of disciplinary matters and the promulgation of Board rules.²⁸

The Board consists of seven members who are dentists, three members who are dental hygienists, and three public members. The Governor appoints each member for a four-year term, and members are not to exceed two terms. ²⁹

All members of the Board are required to be residents of the State of Colorado, and professional members must be currently licensed as a dentist or dental hygienist with at least five years of clinical practice prior to appointment. ³⁰

²⁹ § 12-220-105(1)(b), C.R.S.

²⁸ § 12-220-106, C.R.S.

³⁰ § 12-220-105(2), C.R.S.

During fiscal years 14-15 through 18-19, no program expenditures were reported and no full-time equivalent employees were dedicated by the Division to specifically oversee the two scope of practice elements under review.

Interim Therapeutic Restorations

A dental hygienist may perform ITR in order to stabilize the tooth for both adults and children.³¹ This process may include:

- Utilization of hand instruments to remove soft tissue on the tooth; and
- Placement of glass ionomer as a restorative material.

In Colorado, any dental hygienist interested in placing ITR must obtain a permit from the Board. Section 12-220-128, C.R.S., describes the components to qualify for a permit to place ITR:

- Hold a license in good standing to practice dental hygiene in Colorado;
- Complete a postsecondary course under direct supervision of a faculty member of a dental or hygiene school accredited by the Commission on Dental Accreditation or its successor agency. All clinical evaluations must be completed by dentists who are faculty at an accredited dental or dental hygiene school;
- Carry professional liability insurance in an amount of not less than \$50,000 per claim and an aggregate liability for all claims during a calendar year of not less than \$300,000, unless eligible for a waiver of liability insurance. Coverage may also be maintained through the supervising dentist;³² and
- Complete at least 2,000 hours of supervised, or 4,000 hours of unsupervised general dental hygiene practice after initial licensure, or a combination of hours as determined by the Board.

Additionally, the requirement to submit proof of hours of dental hygiene practice may be waived by the Board for a dental hygienist who performs ITR under the direct supervision of a dentist.³³ Dental hygienists may not use any anesthesia to perform an ITR procedure.³⁴

Dental hygienists may only perform an ITR as a part of a collaborative agreement with a dentist, in which the dentist has provided a diagnosis, treatment plan and instructions to perform the ITR. If the dental hygienist is placing an ITR in any location other than the supervising dentist's office location, the dental hygienist must:³⁵

³¹ 3 CCR § 709-1-1.25 (A), Colorado Dental Board Rules and Regulations.

³² 3 CCR § 709-1-1.3-E-2-a, Colorado Dental Board Rules and Regulations.

³³ § 12-220-128(2), C.R.S.

³⁴ § 12-220-128(3), C.R.S.

³⁵ § 12-220-128(4), C.R.S.

- Provide the patient or patient's representative with notification in writing that the procedure was performed at the direction of the supervising dentist, and will include the dentist's name, physical location, address, and phone number; and
- If the diagnosis, treatment plan, and instructions to perform the ITR were relayed by the dentist utilizing telehealth by store-and-forward transfer (data transfers for review at a later time), the dental hygienist must notify the patient of their right to receive interactive communication with the dentist upon request, either at the time of the consultation or within 30 days.

Further, a dental hygienist must provide written notification to the patient or patient's representative that ITR is a temporary repair, and follow-up care with a dentist is necessary.³⁶

A dentist may supervise no more than five dental hygienists to place ITR under telehealth supervision. The supervising dentist must also have a physical practice location in Colorado in order to provide follow-up care.³⁷

For a dental hygienist to receive a permit to place ITRs, a one-time application must be submitted with no renewals required. Additionally, there are no fees associated with obtaining a permit.

Table 1 illustrates the number of active dental hygienist permits to perform ITR for fiscal years 14-15 through 19-20. The permit process for ITR began in fiscal year 16-17.

Table 1 **Permit Information**

Fiscal Year	Number of Permits Issued
16-17	23
17-18	9
18-19	34
19-20	19

The table indicates that there are currently a total of 85 dental hygienists in Colorado who have received a permit authorizing them to perform ITRs. The Division was unaware of any direct reason regarding the reduced number of permits issued in fiscal year 17-18.

ITR and SDF procedures are performed by dental hygienists who work for or with both private dental providers and federally qualified health centers.

³⁶ § 12-220-128(7), C.R.S.

³⁷ § 12-220-128(6), C.R.S.

For treatments performed utilizing Medicaid funds, private dental providers performed 12 ITR treatments in fiscal year 18-19, and no ITR was performed by private dental providers in fiscal year 19-20. These treatment figures do not include the number of ITRs that may have been paid for by private insurance or by the patients themselves.

Federally qualified health centers also provide ITR to patients. In fiscal year 18-19, 22 ITRs were provided to patients, and in fiscal year 19-20, 11 ITRs were provided to patients utilizing Medicaid funds.

Silver Diamine Fluoride

SDF is a U.S. Food and Drug Administration-approved topical treatment which halts the progression of decay and may prevent further decay in the affected tooth following application.

Unlike the application of ITR, there is no permitting process required for a dental hygienist to apply SDF. However, dental hygienists must comply with specific requirements. In order for a dental hygienist in the state of Colorado to apply SDF, the practitioner must:³⁸

- Hold a license in good standing to practice dental hygiene in Colorado;
- Complete a postsecondary course that meets the requirements of the Board. The course must be at a minimum one hour in length, with live and interactive instruction, and must include specific training including the protocols, limitations, and follow-up mechanisms for the application of SDF;³⁹
- Carry professional liability insurance in an amount of not less than \$50,000 per claim and an aggregate liability for all claims during a calendar year of not less than \$300,000, unless eligible for a waiver of liability insurance. Coverage may also be maintained through the supervising dentist;⁴⁰ and
- Have a collaborative agreement in place with a dentist that describes the protocols, limitations, follow-up and referral processes, and any other requirements established by the Board.

Additionally, if the application of SDF occurs at a location other than the dentist's office location, the dental hygienist must provide in writing to the patient or patient's representative notification that the procedure is being provided in collaboration with a dentist, and must provide the name, address, and phone number of the dentist.⁴¹

³⁹ 3 CCR § 709-1-1.26-B-2, Colorado Dental Board Rules.

³⁸ § 12-220-129(1), C.R.S.

⁴⁰ 3 CCR § 709-1-1.3-E-2-a, Colorado Dental Board Rules.

⁴¹ § 12-220-129(2)(a), C.R.S.

If the dental hygienist utilizes telehealth collaboration with a dentist, the patient or patient's representative must be notified of their right to communicate with the dentist upon request, either at the time of the initial consultation or within 30 days.⁴²

Based solely upon the utilization of Medicaid funds, private dental providers applied 177 SDF treatments in fiscal year 18-19, and 778 SDF treatments in fiscal year 19-20. These figures do not include the number of SDF treatments that may have been paid for by private insurance or by patients themselves.

Federally qualified health centers also utilize the application of SDF with their patients. In fiscal year 18-19, 53 SDF treatments were provided to patients, and in fiscal year 19-20, 138 SDF treatments were provided to patients utilizing Medicaid funds.

Complaint and Disciplinary Activity

The seventh sunset criterion requires COPRRR to examine whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

During the years reviewed, no complaints were received nor were any violations found by the Board specific to either the application of ITR or SDF by dental hygienists in Colorado. As a result, no disciplinary action was taken.

Fining Activity

The seventh sunset criterion requires COPRRR to examine whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

According to section 12-220-106(1)(b)(D), C.R.S., the Board may issue administrative fines for a violation of the Act. During the years reviewed, no fines were issued by the Board specific to either the application of ITR or SDF by dental hygienists in Colorado.

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⁴² § 12-220-129(2)(b), C.R.S.

Collateral Consequences - Criminal Convictions

The ninth sunset criterion requires COPRRR to examine whether the agency under review, through its licensing processes, imposes any sanctions or disqualifications based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Board possesses the authority to impose sanctions and disqualifications against the license of a practitioner based upon criminal history. During the years reviewed, no sanctions were imposed specific to either the application of ITR or SDF by dental hygienists in Colorado.

Analysis and Recommendations

The final sunset criterion questions whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest. The recommendations that follow are offered in consideration of this criterion, in general, and any criteria specifically referenced in those recommendations.

Recommendation 1 - Continue the regulation of the application of interim therapeutic restoration by dental hygienists.

In 2015, House Bill 15-1309 was enacted by the General Assembly, which authorized dental hygienists to place interim therapeutic restorations (ITR) under the direct or indirect supervision of a dentist utilizing telehealth technology. Since that time, dental hygienists who receive the required training can work in collaboration with dentists to provide ITR treatments to patients across Colorado.

The use of ITR as a treatment option removes and helps to prevent further tooth decay. This process typically involves a partial removal of tooth decay utilizing hand instruments with no anesthesia needed, and the removed portion of the decayed tooth is typically replaced with a durable glass ionomer material.

This treatment expands options for consumers to receive critical dental care interventions, especially children and elderly patients who may not have access to financial resources or may live in rural areas, which may increase challenges to receiving timely critical care to prevent further decay.

The ITR procedure may have the possibility to create additional harm to patients if not performed properly. For instance, improper diagnosis or application of the restoration could cause damage to the tooth structure, which is why it is so important to correctly ascertain when the placement of an ITR is appropriate.

As a result, the ITR procedure requires additional training, coursework, and permitting beyond the traditional dental hygiene license requirements to ensure that dental hygienists performing this procedure are able to do so with minimal competency.

ITR procedures are performed by dental hygienists who work for or with both private dental providers and federally qualified health centers. The total performed by both groups in Colorado that received Medicaid reimbursement was 34 ITR procedures in fiscal year 18-19, and 11 ITR procedures in fiscal year 19-20.

During fiscal year 19-20, the Medicaid reimbursement rate was \$50.78 per ITR procedure. In contrast, the reimbursement rates for amalgam fillings ranged from approximately \$84.42 to \$150.05, and for resin fillings ranged from \$97.27 to \$178.06

that same fiscal year. These data indicate that ITR is a cost-effective option when compared with traditional filling treatments where applicable.

The first sunset criterion asks if regulation is necessary to protect the public health, safety and welfare. The incorporation of ITR into the variety of available treatment options enables Coloradans to receive critical interventions that may protect them from further deterioration of their oral health, and these treatment options strengthen community access to important dental care treatment for Coloradans. Therefore, the General Assembly should continue the regulation of ITR performed by dental hygienists.

Recommendation 2 - Continue the regulation of the application of silver diamine fluoride by dental hygienists.

In 2018, the General Assembly passed legislation which expanded the scope of practice for dental hygienists to allow for the application of silver diamine fluoride (SDF) under the direct or indirect supervision of a collaborating dentist utilizing telehealth technology.

SDF is an FDA-approved, topical treatment which halts the progression of decay and may prevent further decay in the affected tooth following application. Dental hygienists can receive additional training to apply SDF through a training course that is typically one hour in length. This expands options for consumers to receive critical dental care interventions, especially children and elderly patients who may not have access to financial resources or may live in rural areas.

Although the risks of harm associated with the application of SDF are low, the product can cause permanent staining or darkening of the decayed portion of the tooth. However, it does not cause staining if applied on healthy teeth or portions of a tooth that do not have decay. Additional precautions may also be taken into account with patients that are allergic to silver or are exhibiting symptoms of advanced gum disease.

As a result, the SDF procedure requires some additional training beyond the traditional dental hygiene license requirements to ensure that dental hygienists performing this procedure are able to do so with minimal competency.

SDF treatments are performed by dental hygienists who work for or with both private dental providers and federally qualified health centers. The total performed by both groups in Colorado that received Medicaid reimbursement was 230 SDF procedures in fiscal year 18-19, and 916 SDF procedures in fiscal year 19-20.

During fiscal year 19-20, the Medicaid reimbursement rate was \$5.53 per SDF treatment. In contrast, the reimbursement rates for amalgam fillings ranged from approximately \$84.42 to \$150.05, and resin fillings ranged from \$97.27 to \$178.06 per treatment that same fiscal year. These data indicate that SDF treatment is cost-effective when compared to traditional filling treatments where applicable.

The first sunset criterion asks if regulation is necessary to protect the public health, safety and welfare. The use of SDF in Colorado provides an important treatment option to treat and prevent tooth decay. Further, the utilization by dental hygienists of SDF enables Coloradans to receive critical interventions that may protect them from further deterioration of their oral health, which increases public welfare. Therefore, the General Assembly should continue the regulation of SDF application by dental hygienists.

Recommendation 3 - Combine future sunset reviews of both ITR and SDF with the sunset review of the Dental Practice Act.

The authorizations that enable dental hygienists to apply both ITR and SDF are newly included provisions within the Dental Practice Act (Act), and may require additional modifications as these scope of practice elements further develop. Additionally, since both statutory provisions are part of the larger scope of practice for dental hygienists, they do not require a sunset provision separate from the Act.

The tenth sunset criterion asks,

Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

By combining the sunset review date for these two scope of practice provisions with that of the Act, these two provisions would be evaluated as a part of the larger scope of practice which could then be reviewed holistically, creating additional efficiencies in the sunset review process, as well as for Board staff, which is in the public interest.

The Act is scheduled to repeal on September 1, 2025, and the review will occur in 2024. Therefore, the General Assembly should remove the separate sunset provisions for the application of ITR and SDF by dental hygienists, which will allow for a comprehensive and holistic review of the Act in 2024.

Recommendation 4 - Repeal the language in sections 12-220-128(1)(c) and 12-220-129(1)(c), C.R.S., regarding liability insurance.

Both section 12-220-128(1)(c), C.R.S., and section 12-220-129 (1)(c), C.R.S., state that one of the requirements for a dental hygienist to apply either ITR or SDF is that the applicant,

Carries current professional liability insurance in the amount specified in section 12-220-147...

Section 12-220-147, C.R.S., already requires dental hygienists to carry liability insurance, and no additional liability insurance is required to apply either ITR or SDF.

Therefore, this inclusion is redundant and confusing to both practitioners and consumers.

The tenth sunset criterion asks,

Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Since the duplication in statute of the same liability insurance requirement is redundant and may lead to misinterpretation and confusion from both practitioners and members of the public, the General Assembly should repeal sections 12-20-128(1)(c) and 12-220-129(1)(c), C.R.S.

Recommendation 5 - Amend sections 12-220-128(4)(c) and 12-220-129(2)(b), C.R.S., regarding the utilization of "store and forward transfer" technology to allow for the use of synchronous technologies in telehealth applications relating to ITR and SDF.

There are many technologies available for telehealth communication between dentists and dental hygienists to relay patient information in a secure manner. Some are synchronous, meaning that they allow collaborative work to be accomplished in real-time, while other technologies are asynchronous, meaning that the patient records are viewed by the dentist at a later time.

Both sections 12-220-128(4)(c) and 12-220-129(2)(b), C.R.S address the use of asynchronous technologies only, and refer to this type of patient information relay as, "store-and-forward transfer". For example, section 12-220-128(4)(c), C.R.S., states:

A dental hygienist who obtains a dentist's diagnosis, treatment plan, and instruction to perform an ITR utilizing telehealth by store-and-forward transfer shall notify the patient of the patient's right to receive interactive communication with the distant dentist upon request.

This statutory language is confusing, since these provisions only address the use of asynchronous store-and-forward transfer forms of technology to relay patient information. Since statute does not address the use of synchronous technology, it may be perceived that asynchronous technologies are the only methods allowable for sharing patient information between dentists and dental hygienists in telehealth.

By expanding the definition regarding the types of data transfer allowable for use in these dental telehealth applications, dental hygienists and dentists may be able to work collaboratively in real-time utilizing synchronous technologies, which in some instances, may reduce the number of visits required for a patient to receive treatment.

The second and eighth sunset criteria ask:

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest; and

Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel...

The expansion of the statutory language to allow for both synchronous and asynchronous collaboration as long as patient privacy is maintained would be a less restrictive form of regulation, and could adapt over time as new technologies emerge. Additionally, the ability to more frequently complete ITR and SDF procedures in one visit through the use of synchronous technology could lead to a better optimization of personnel, and would benefit the consumer by potentially reducing office visits.

Therefore, the General Assembly should modify this statutory language to allow for both synchronous and asynchronous collaboration with the purpose of potentially increasing efficiency for dental telehealth in the performance of ITR and SDF treatments.

Recommendation 6 - Remove statutory language from sections 12-220-128(4)(c) and 12-220-129(2)(b), C.R.S., regarding the method of communication with the distant dentist, and authorize the Board to develop related rules if needed in the future.

Both ITR and SDF statutes contain nearly identical language regarding the method in which a patient may communicate with a distant dentist. Section 12-220-128(4)(c), C.R.S. states,

A dental hygienist who obtains a dentist's diagnosis, treatment plan, and instruction to perform an ITR utilizing telehealth by store-and-forward-transfer shall notify the patient of the patient's right to receive interactive communication with the distant dentist upon request. Communication with a distant dentist may occur either at the time of the consultation or within thirty days after the dental hygienist notifies the patient of the results of the consultation.

This establishment in statute regarding a specific timeframe for communication with a distant dentist is cumbersome, confusing, and arbitrary.

First, this language is unclear regarding whose responsibility it is to establish the communication with the patient. Is it the dentist, the patient, or the dental hygienist who performed the procedure who is required to schedule this communication between the distant dentist and the patient? Statute is silent on this issue, which stakeholders have indicated is confusing for both practitioners and patients alike.

Second, this statutory provision indicates that any communication between the distant dentist and patient may occur within 30 days of the initial consultation. This language is ambiguous since it does not require any specific form of communication.

The second and tenth sunset criteria ask,

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest...; and

Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Statutory sections authorizing both ITR and SDF require that the supervising dentist's name, practice location address, and telephone number are provided to the patient. This indicates that follow-up care mechanisms should be available to each patient should they have questions or concerns regarding their dental health following any ITR or SDF procedure. Yet, due to the arbitrary restrictions and confusing statutory language placed upon future communications between the distant dentist and the patient, the opposite result may occur, in which a patient may not feel comfortable reaching out to the distant dentist due to lack of clarity regarding how this form of communication may be instigated, and the timeframe in which statute suggests this communication should occur.

By removing this language from both the ITR and SDF sections of statute, any potential confusion regarding the timeframe for communication between the distant dentist and the patient would be eliminated, which would benefit patients and would better serve the public interest. Additionally, the Board should be authorized to develop rules related to communication between the dentist and patient if needed to clarify this requirement in the future.

Therefore, the General Assembly should remove statutory language from sections 12-220-128(4)(c) and 12-220-129(2)(b), C.R.S., regarding the method of communication with the distant dentist, and authorize the Board to develop related rules if needed in the future.

Recommendation 7 - Amend section 12-220-128(7), C.R.S., regarding the informed consent required to perform ITR.

Section 12-220-128(7), C.R.S., states that a general requirement for the application of ITR includes that,

A dental hygienist shall inform the patient or the patient's legal guardian, in writing, and require the patient or the patient's legal guardian to acknowledge by signature, that the interim therapeutic restoration is a

temporary repair to the tooth and that appropriate follow up care with a dentist is necessary.

First, this statutory language may create confusion among patients. ITR therapies have been proven to have the ability to maintain their efficacy for extended periods of time, and may even remain functional for years as an effective treatment. The requirement that the dental hygienist explain that ITR "is a temporary repair" creates an unnecessary sense of urgency, which a patient may interpret as meaning that they need to see a dentist right away to replace the restoration.

Many of the patients who receive ITR may be from underserved populations, such as elderly, homeless, and children who may not have access to financial resources or may live in rural areas. Since both dental hygienists and dentists alike encourage their patients to schedule regular dental check-ups to prevent tooth decay and maintain oral health, it may not be necessary for the patient to immediately schedule a dentist appointment following the procedure, as this statutory language seems to imply.

Further, the statutory language cited discusses the specifics upon which the consent shall be provided to the patient, including that the consent form must be offered in writing, and also requires a signature from the patient or the patient's legal guardian. Instead, additional statutory language should be added to indicate that the dental hygienist shall inform the patient or the patient's legal guardian, "in accordance with rules promulgated by the Board." The Board often addresses issues regarding consent language in rules. Additionally, the Board could hold public meetings if any changes were proposed, which would allow members of the public and other stakeholders to participate in the process.

The second and tenth sunset criteria ask,

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest; and

Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

The aforementioned statutory language is unnecessarily restrictive and confusing by informing patients that the ITR procedure is temporary, and follow-up care is necessary following an ITR procedure. This may lead a patient to schedule an immediate appointment for follow-up with a dentist that may not need to be immediately performed, potentially leading to additional expense and time expended.

Additionally, the Board is comprised of dentists, dental hygienists, and members of the public. By allowing the Board the flexibility to promulgate rules, tailored consent language could be carefully crafted with stakeholder input if any changes were to occur over time, which is in the public interest.

Therefore, the General Assembly should repeal the statutory language indicating ITR is a temporary repair and follow-up care is necessary, and include statutory language indicating that a dental hygienist shall inform the patient or the patient's legal guardian, in accordance with rules promulgated by the Board, that the patient should follow up with a dentist as appropriate.

Recommendation 8 - Amend section 12-220-128(1)(d), C.R.S., regarding the number of hours of experience required to obtain an ITR permit, and direct the Board to determine, by rule, the number of hours required.

Presently, the number of hours of general dental hygiene practice required in section 12-220-128(1)(d), C.R.S., to apply for a permit to perform ITR is as follows:

- (1) Upon application, accompanied by a fee in an amount determined by the [Director of the Division of Professions and Occupations, the [B]oard shall grant a permit to place interim therapeutic restorations to any dental hygienist applicant who,
 - (d) Has completed the following hours of dental hygiene practice as evidenced in documentation required by the board:
 - (I) 2,000 hours of supervised dental hygiene practice after initial dental hygiene licensure;
 - (II) 4,000 hours of unsupervised dental hygiene practice after initial dental hygiene licensure; or
 - (III) A combination of the hours specified in subsections (1)(d)(I) and (1)(d)(II) of this section as determined by the [B]oard by rule.

This requirement is also stated in 3 CCR 709-1-1.25-B-4 of the Colorado Dental Board Rules and Regulations.

Throughout the course of this sunset review, some stakeholders raised this statutory reference as an issue, citing that this requirement may be overly burdensome and restrictive, and that it prevents qualified dental hygienists from being able to receive the ITR permit upon initial licensure. Thus, they maintain, it may limit the pool of permit holders, thus reducing access to this form of treatment for patients throughout Colorado.

Additionally, other stakeholders indicated that any major adjustments to this requirement could potentially negatively impact the dental hygiene general course requirements within dental hygiene schools. For example, if all experience

requirements to apply for an ITR permit were removed, dental hygiene schools would be required to teach the ITR course as a part of the general curriculum for accreditation purposes, since training for ITR would then be considered a part of the general scope of practice. Some stakeholders further expressed that schools are already required to cover a vast amount of material for initial licensure, and in the scenario in which all experience requirements were removed, the requirement to add the ITR course to all dental hygiene programs in the state may be overly burdensome for both students and teachers in dental hygiene programs.

The second, third, and eighth sunset criteria state,

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest...;

Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices...; and

Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel...

The ITR permit process for dental hygienists was only recently established in Colorado (in 2015), and may require additional modifications over time to ensure that the experience requirements reflect the minimum qualifications necessary to perform this procedure.

The Board, comprised of dentists, dental hygienists, and members of the public, possesses the expertise required to determine the necessary qualifications on an ongoing basis. By removing this language from statute and requiring the Board to establish them by rule, any potential changes would be completed by a Board with diverse membership, through a stakeholder process in a public forum, which would be open to participation from all interested members of the public regarding any changes to this requirement.

This change to a less restrictive form of regulation would allow greater flexibility over time by allowing the Board to make adjustments as necessary to this requirement in order to ensure that the use of personnel is maximized, while allowing increased participation from stakeholders, which would better support the public interest.

Therefore, the General Assembly should remove specific language from statute regarding the experience required to obtain an ITR permit, and require the Board to establish experience requirements by rule.

Recommendation 9 - Require all dentists collaborating in ITR procedures under telehealth to hold a Colorado license in good standing, and have either a physical practice location in Colorado, or in a surrounding state within a reasonable travel time considering the point of location of the treatment, for follow-up care.

In order for a dentist to work collaboratively with a dental hygienist to perform ITR, section 12-220-128(6), C.R.S., requires that,

...A dentist who supervises a dental hygienist who provides interim therapeutic restorations under telehealth supervision must have a physical practice location in Colorado for purposes of patient referral for follow-up care.

The requirement of a physical practice location in Colorado has created issues for some rural Colorado dental hygienists who perform ITRs, as well as their rural patients.

For example, stakeholders have indicated that dental hygienists who perform ITR services in rural areas of the state may have difficulties locating a dentist with whom to collaborate since the nearest dentist willing to collaborate may have a physical practice location across the border in a neighboring state. Therefore, dental hygienists in this scenario may be required to seek out a dentist for collaboration with an office in Colorado with a further travel distance, and a longer travel time, to the patient in order to satisfy this statutory requirement.

This situation may also cause undue hardship for patients since the reduction of options for collaboration may reduce the number of dental hygienists able to provide this procedure in rural areas and may reduce accessibility for rural patients.

Additionally, some stakeholders have suggested that the requirement of a physical practice location in Colorado could be modified to allow dentists in surrounding states to collaborate with a dental hygienist within a specific mileage distance to the location in which the ITR procedure was performed. This proposed solution would be arbitrarily chosen and may still not serve the interests of Colorado patients. For example, if it were required that a collaborating dentist in a surrounding state hold a physical practice location within 60 miles from the location where the ITR procedure was performed, then a dentist whose practice is 65 miles away would be eliminated from collaboration by default.

However, it should also be noted that the amount of time that a patient may be willing to travel for follow-up care is subjective. In some rural Colorado communities, an acceptable travel time to a dentist may be 30 minutes, whereas in other rural communities it may be over an hour.

While it is important that the patient have access to follow-up care from the collaborating dentist at a physical location, due to the variability of access from one

rural community to the next, a flexible standard would allow dental hygienists to collaborate with dentists in surrounding states without imposing specific mileage or travel time restrictions.

Additionally, if the language regarding the requirement for a physical practice location in Colorado is amended, specific statutory language requiring that all collaborating dentists hold a Colorado license is needed. All collaborating dentists would then be under the jurisdiction of both the Board and the provisions of the Act. In other words, a Colorado license in good-standing should be required of all dentists who collaborate with dental hygienists to perform ITR procedures in Colorado.

The second, sixth, and tenth sunset criteria ask,

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest...;

...whether the agency stimulates or restricts competition; and

Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

By reducing these statutory restrictions to allow dentists in surrounding states to collaborate with dental hygienists to perform ITR, telehealth collaborations may become more accessible for both dental hygienists and patients alike.

Additionally, by requiring that all collaborating dentists hold a license to practice in Colorado, minimum competencies could be regulated by the Board, which would further support the public interest.

Therefore, the General Assembly should require all dentists collaborating in ITR procedures under telehealth to hold a Colorado license in good standing and have either a physical practice location in Colorado, or in a surrounding state within reasonable travel time considering the point of location of the treatment, for follow-up care.

Recommendation 10 - Direct the Board to develop a waiver process to allow dentists to supervise more than five dental hygienists who perform ITR.

Section 12-220-128(6), C.R.S., places a specific cap on the number of dental hygienists performing ITR that a dentist can supervise,

A dentist shall not supervise more than five dental hygienists who place interim therapeutic restorations under telehealth supervision.

During the course of this sunset review, stakeholders indicated that the amount of time dental hygienists spend performing ITR procedures varies widely; some dental hygienists perform ITR on a consistent basis while others may only provide ITR treatments a few days per month.

Presently, dentists can only supervise up to five dental hygienists who perform ITR. However, since some dental hygienists may spend less time performing the procedure than others, the amount of supervision required may be less for those who perform ITRs in a reduced capacity, and some dentists may be able to supervise more than five dental hygienists who perform the procedure.

By amending the statute to allow a dentist to supervise up to five dental hygienists, and potentially over five with a waiver approved by the Board, dentists will have additional flexibility in determining the appropriate number of dental hygienists that they can supervise under telehealth. This change may also improve the ability of dental hygienists to locate a dentist with whom they can collaborate since not all dentists supervise this type of procedure.

Additionally, by authorizing the Board to develop a waiver process and specific requirements for the approval of a waiver in Board rule, the waiver process can be more flexible than if placed in statute, and can change over time as this relatively new type of telehealth supervision evolves. However, the Board would still have the ability to determine if a request for a waiver meets necessary requirements. Doing so allows the Board to reach decisions regarding the circumstances of each waiver request and what would constitute competent supervision.

It should be noted that this type of waiver process is utilized in other practice acts as a way to expand flexibility and options for supervision. For example, a licensed physician can supervise additional physician assistants for certain types of supervision if approved through a waiver process established by the Colorado Medical Board.⁴³

The second, third and eighth sunset criteria ask,

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest...;

Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters; and

Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel...

⁴³ 3 CCR § 713-7-7.1(F). Colorado Medical Board, Rules and Regulations Regarding the Licensure of and Practice by Physician Assistants.

This statutory cap allowing dentists to supervise a maximum of five dental hygienists who perform ITR is arbitrary. Some dentists may have the professional capacity to supervise more. However, any attempt to raise the cap would be an arbitrary number selection as well. Evaluating each request for additional supervision would allow dentists to tailor their supervision capacity in accordance with Board rules, which is a less restrictive form of regulation.

Through the development of a waiver process, dentists and dental hygienists would have increased flexibility in their ability to collaborate in a telehealth capacity, which could better optimize the use of personnel and potentially increase telehealth options, expanding choices for consumers.

The current statute is unnecessarily restrictive, and may hinder the ability of dentists who are willing to participate in a collaborative agreement with a dental hygienist performing ITR. By developing a waiver process in which the application and rules are determined by the Board, greater flexibility could be achieved in supervisory processes, while establishing rules to ensure that required components of supervision are met, which would protect the public interest.

Therefore, the General Assembly should direct the Board to develop a waiver process for dentists to supervise additional dental hygienists over the five supervisees currently permitted in statute, and direct the Board to develop rules that establish the application and requirements for the waiver.

Recommendation 11 - Amend section 12-220-129, C.R.S., to indicate that an articulated plan must be developed by dental hygienists in order to apply SDF, and repeal language requiring a collaborative agreement.

In 2018, the General Assembly established section 12-220-129, C.R.S., which expanded the scope of practice for dental hygienists to allow for the application of SDF under the direct or indirect supervision of a collaborating dentist utilizing telehealth technology.

Section 12-220-129, C.R.S., makes multiple references to the requirement that dental hygienists must establish a collaborative agreement with a supervising dentist. Collaborative agreements typically require the supervisee to discuss any procedure with a supervisor prior to the application of the treatment, which may then require additional office visits in instances where the dental hygienist is applying SDF in a location outside of the dentist's office.

SDF is a topical, FDA-approved, low-risk antibacterial treatment that halts the progression of tooth decay, and may also help to prevent further tooth decay. The training required for its use is only approximately one hour in length, indicating that the application of SDF is closely aligned with the skills received in general training for

a dental hygienist. It should also be noted that no complaints were received regarding the application of SDF during the years reviewed. Therefore, the requirement for a collaborative agreement is overly restrictive.

If the statute were amended to allow for the development of an articulated plan, rather than a collaborative agreement, dental hygienists would still work with a dentist to develop a plan for SDF use, including any restrictions or limitations, protocols, follow-up and referral mechanisms, and any other requirements established by the Board. Dental hygienists could then follow the processes established in the articulated plan for application of SDF, and would still have the ability to discuss more complex cases with a dentist prior to SDF application as needed, but would not be required by statute to discuss each application in advance with a supervising dentist.

The second and eighth sunset criteria ask,

If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest...; and

Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel...

Since SDF has a low risk of harm, and no complaints have been received regarding its use, modifying the statutory requirement to allow for the development of an articulated plan with a dentist rather than a collaborative agreement would be a less restrictive form of regulation that would allow dental hygienists to be better utilized, potentially increasing access to this important dental treatment for consumers.

Therefore, the General Assembly should amend section 12-220-129, C.R.S., to indicate that an articulated plan must be developed between a dentist and a dental hygienist in order to apply SDF, and repeal statutory language regarding the collaborative agreement requirement.

Administrative Recommendation 1 - The Board should modify the SDF course requirement to allow for on-demand course completion.

Board Rule 3 CCR 709-1-1.26-B-2 requires that applicants,

Successfully complete training that covers a minimum of one hour of live and interactive instruction...

This rule further clarifies that the one-hour course must cover topics including the proper application, limitations, and diagnostic criteria involved in applying SDF, as well as any required safety protocols and follow-up procedures.

Since SDF is a topical application with a low risk of harm and similar in procedure to the application of other topical agents such as fluoride, which dental hygienists can also apply, the instruction required for a dental hygienist to be competent is only approximately one hour in length.

Throughout the course of this sunset review, stakeholders maintained that the requirement that this course be completed in a live and interactive way, as is stipulated in Board rule, creates issues for some licensees with respect to course accessibility, as many dental hygienists that live and work in rural communities may have difficulties in travelling to an in-person course.

Additionally, in instances where an interactive course may be offered in an online format, a dental hygienist may still potentially need to structure their availability or wait for a course that works with their schedule before being able to apply SDF.

The eighth sunset criterion asks,

Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel...

By modifying this Board rule to allow for live, interactive, or on-demand instruction for course completion, accessibility will be increased for licensees who would benefit from on-demand coursework that fits their schedule, while still allowing for live and interactive instruction to take place for those licensees who would prefer more interactive methods of learning.

This modification would also benefit consumers since practitioners would have easier access to the course, potentially increasing the number of dental hygienists who are trained to apply SDF in Colorado. Therefore, the Board should modify the SDF course requirement to allow for on-demand completion of the required SDF course in Board rules.