PROPOSED DRUG REGULATION – *PRESCRIBING, DISPENSING, COMPOUNDING AND SELLING OF DRUGS*
College of Dental Hygienists of Ontario

This proposed regulation is new. The following chart breaks out each section of the regulation and provides a rationale for its inclusion in the proposed regulation.

Reg. Section	Proposed Clause	Rationale
S. 1.	PRESCRIBING, DISPENSING, SELLING AND COMPOUNDING A DRUG (1) A member shall not engage in conduct that results, directly or indirectly, in a personal or financial benefit that conflicts with his or her professional or ethical duty to a patient as a result of prescribing, dispensing, selling or compounding a drug. (2) A member who prescribes, dispenses, sells or compounds a drug shall comply with all applicable federal and provincial law related to prescribing, dispensing, selling or compounding a drug. (3) A member shall not delegate the performance of prescribing a drug to any other person. (4) Subject to the other provisions of this section, it is a standard of practice of the profession that a member who prescribes, dispenses, compounds or sells a drug designated in this regulation shall first have successfully completed relevant training in pharmacology which has been approved by the Council. (5) Despite subsection (4), a member may prescribe, dispense, compound or sell a drug designated in in this regulation, if, (a) the action is done as part of training approved by the Council; and (b) the action is performed under the supervision of a member who is authorized under this regulation to prescribe, dispense, compound and sell the drug.	This clause outlines the professional obligations of a registered dental hygienist in Ontario who may be engaged in the prescribing dispensing, selling or compounding of a drug.
S. 2.	PRESCRIBING For the purposes of paragraph 3 of section 4 of the Act, a member may only prescribe an (a) anti-microbial rinses, chips, microspheres, lozenges or other topical delivery system, including sub-gingival and sub-lingual delivery systems, of the microbials listed in Schedule 1 in the course of engaging in the practice of dental hygiene,	This section articulates the terms and conditions that must be observed before a registered dental hygienist may *prescribe* the two drugs covered under this regulation. The two drugs include chlorhexidine (an antimicrobial drug) and fluoride (an anticariogenic drug). Antimicrobials kill or inhibit the growth of microorganisms such as bacteria, fungi and protozoans.

	(b) anticariogenics listed in Schedule 1 in the course of engaging in the practice of dental hygiene, if all of the following conditions are met: 1. The member must have a dental hygiene-patient relationship with the patient for whom the drug is prescribed. 2. The member must prescribe the drug for therapeutic purposes only. 3. The member must ensure that the following information is recorded on the prescription: i. the name and address of the person for whom the drug is prescribed, ii. the name, strength (where applicable) and quantity of the drug that is prescribed, iii. the directions for use, iv. the member's name, address, telephone number, title and registration number issued by the College, v. the member's signature, vi. the date on which the drug is prescribed, and vii. the number of refills, if applicable. 4. The member must retain a copy of the information recorded on the prescription required under paragraph 3 as part of the patient's health record.	An anticariogenic drug is intended to prevent or manage caries. Dental caries, also known as tooth decay or a cavity, is an infection, bacterial in origin, that causes demineralization and destruction of the hard tissues (enamel, dentin and cementum), usually by production of acid by bacterial fermentation of the food debris accumulated on the tooth surface. The most common anticariogenic drug is fluoride.
S. 3.	DISPENSING For the purposes of paragraph 3 of section 4 of the Act, a member may only dispense an (a) anti-microbial rinses, chips, microspheres, lozenges or other topical delivery system, including sub-gingival and sub-lingual delivery systems, of the microbials listed in Schedule 1 in the course of engaging in the practice of dental hygiene, (b) anticariogenics listed in Schedule 1 in the course of engaging in the practice of dental hygiene, if all of the following conditions are met: 1. The member must have a dental hygiene-patient relationship with the patient for whom the drug is dispensed. 2. The member must not dispense a drug pursuant to a prescription issued by any other person. 3. The member must provide the drug directly to the patient or the patient's representative.	This section articulates the terms and conditions that must be observed before a registered dental hygienist may *dispense* the two drugs covered under this regulation.

	4. The member must dispense the drug for therapeutic purposes only. 5. The member must dispense a reasonable quantity of the drug having regard to the therapeutic purpose described in paragraph 4. 6. The member must have reasonable grounds to believe that the drug has been obtained and stored in accordance with any applicable legislation. 7. The member must be satisfied that the drug has not expired and will not expire before the date on which the patient is expected to take the last of the drug. 8. The member must ensure that the container in which the drug is dispensed is marked with, i. an identification number, if applicable, ii. the member's name and title, iii. the name, address and telephone number of the place from which the drug is dispensed, iv. the identification of the drug as to its name, its strength (where applicable) and, if available, its manufacturer, v. the quantity of the drug dispensed, vi. the date the drug is dispensed, vii. the expiry date of the drug, if applicable, viii. the name of the patient for whom the drug is dispensed, and ix. the directions for use. 9. The member must retain a copy of the information set out under paragraph 8 on the container in which the drug was dispensed in the patient's health record, along with the information documenting compliance with the conditions described in paragraphs 1 and 4.	
S. 4.	COMPOUNDING For the purposes of paragraph 3 of section 4 of the Act, a member may only compound an (a) anti-microbial rinses, chips, microspheres, lozenges or other topical delivery system, including sub-gingival and sub-lingual delivery systems, of the microbials listed in Schedule 1 in the course of engaging in the practice of dental hygiene, (b) anticariogenics listed in Schedule 1 in the course of engaging in the practice of dental hygiene, if all of the following conditions are met:	This section articulates the terms and conditions that must be observed before a registered dental hygienist may *compound* the two drugs covered under this regulation. Compound is the scientific term for mixing two drugs to produce another drug. In the case of an antimicrobial (chlorhexidine), a dental hygienist is effectively creating a medicated mouthwash from two already prepared drugs, i.e., s/he is not compounding a drug from raw materials.

	1. The member must only compound two or more drugs to produce a compounded drug. 2. The member must ensure that the compounded drug is for topical use only and for therapeutic purposes. 3. The member must have a dental hygiene-patient relationship with the patient for whom the drug is compounded. 4. The member must dispense the compounded drug to the patient or his or her representative or apply it directly to the patient. 5. The member must have reasonable grounds to believe that the drugs used in the compounding have been obtained and stored in accordance with any applicable legislation. 6. The member must be satisfied that the drugs used in the compounding have not expired and will not expire before the date on which the patient is expected to apply the last of the compounded drug. 7. The member must ensure that the container holding the drug is marked with, i. an identification number, if applicable, ii. the name and title of the member, iii. the name, address and telephone number of the place in which the drug was compounded, iv. the identification of the substances used in the compounded drug, their names, strength and manufacturer, v. the percentage of each of the drugs used to make the compounded drug and the quantity placed in the container, vi. the date the drug was compounded and the date the compounded drug was dispensed, if different from the former date, vii. the expiry date of the compounded drug, viii. the name of the patient for whom the drug was compounded, and ix. the directions for use. 8. The member must retain a copy of the information set out under paragraph 7 in the patient's health record, along with the information documenting compliance with the conditions described in paragraphs 2 and 3.	

S. 5.	SELLING (1) For the purposes of paragraph 3 of section 4 of the Act, a member may only sell an (a) anti-microbial rinses, chips, microspheres, lozenges or other topical delivery system, including sub-gingival and sub-lingual delivery systems, of the microbials listed in Schedule 1 in the course of engaging in the practice of dental hygiene, (b) anticariogenics listed in Schedule 1 in the course of engaging in the practice of dental hygiene, if all of the following conditions are met: 1. The member must have a dental hygiene-patient relationship with the patient to whom the drug is sold. 2. The member must sell the drug for therapeutic purposes only and only if he or she dispenses the drug directly to the patient or the patient's representative or the drug is administered to the patient. 3. The member must have reasonable grounds to believe that the drug has been obtained and stored in accordance with any applicable federal or provincial legislation. 4. The member must be satisfied that the drug has not expired and will not expire before the date on which the patient is expected to take the last of the drug. 5. The member must not sell a drug if the selling provides a profit to him or her or a direct or indirect personal or financial benefit, other than the actual cost of the drug. 6. The member must retain in the patient's health record a record that the drug was sold to the patient, the price charged and the information documenting compliance with the conditions described in paragraphs 1 and 2. (2) A dental hygienist shall not describe himself or herself orally or in writing as a person who is authorized to sell a drug unless he or she states that such drug can only be sold to a person with whom the dental hygienist has a dental-hygiene-patient relationship.	This section articulates the terms and conditions that must be observed before a registered dental hygienist may *sell* one of the two drugs covered under this regulation.

Schedule 1.	Anticariogenics Fluoride and its salts Antimicrobial Chlorhexidine and its salts	This section specifies the two drugs that are covered under this regulation: antimicrobials and anticariogenics. Antimicrobials kill or inhibit the growth of microorganisms such as bacteria, fungi and protozoans. An anticariogenic drug is intended to prevent caries or in some cases re-mineralize a tooth. Dental caries, also known as tooth decay or a cavity, is an infection, bacterial in origin, that causes demineralization and destruction of the hard tissues (enamel, dentin and cementum), usually by production of acid by bacterial fermentation of the food debris accumulated on the tooth surface. The most common anticariogenic drug is fluoride.
S. 6.	USING DRUGS In accordance with subsection 118(3) of the Drug and Pharmacies Regulation Act, a member may use in the course of engaging in the practice of dental hygiene the following drugs: (a) an anti-microbial drug administered orally or topically including sub-gingival or sub-lingual delivery systems, (b) an anticariogenic drug administered orally or topically including sub-gingival or sub-lingual delivery systems, (c) an anaesthetic drug administered topically including sub-gingival or sub-lingual delivery systems, and (d) any drug that may, without a prescription, be lawfully purchased or acquired if it is administered orally or topically including sub-gingival or sub-lingual delivery systems.	This section articulates the mode in which a registered dental hygienist may administer an antimicrobial or an anticariogenic drug. This section also reconfirms existing legislation, i.e,, the Drug and Pharmacies Regulation Act. Oral delivery of a drug refers to a drug that a patient/client ingests orally. Topical delivery refers to a drug that is applied directly to tissue or teeth. Gingiva is the scientific term that oral health professionals used for gums. Sub-gingival is the term used to describe that part of the gum that lies slightly below the surface and adjacent to the tooth. Sub-gingival delivery refers to the application of a drug to that portion of the gum. Lingual is the scientific term that oral health professionals use for the tongue. Sub-lingual delivery, therefore, is the application of a drug beneath the tongue.