

FLORIDA DENTAL ASSOCIATION

**GOVERNMENTAL ACTION COMMITTEE**

**AGENDA**

DATE: Tuesday, August 10, 2021  
NOTICED START TIME: 1:00 p.m. EST  
PROJECTED END TIME: 2:00 p.m. EST  
LOCATION: Conference Call

**CONFERENCE CALL DIRECTIONS**

1. CALL 1-951-797-1058
  2. ENTER CONFERENCE CODE: 982799
- ANNOUNCE YOUR ENTRY ONTO THE CALL**

CHAIR: Dr. Dave Boden, FDA President

COMMITTEE MEMBERS:

Dr. Gerald Bird, Member / President-elect	Dr. Queanh Phan, Member / WCDDA
Dr. Andy Brown, Member / IPP	Dr. Gabriel Quinones, Member / SFDDA
Dr. Joe Calderone, Member / BOD Liaison	Dr. Jeff Ottley, Member / NWDDA
Dr. Dan Gesek, Member / NEDDA	Dr. Jay Singer, Member / ACDDA
Dr. Steve Hochfelder, Members / CFDDA	

CONSULTANTS:

Dr. Zack Kalarickal  
Dr. Jason Larkin  
Dr. Rudy Liddell  
Dr. John Paul  
Dr. Rachel Perez  
Dr. Beatriz Terry

STAFF:

Drew Eason, Executive Director	Casey Stoutamire, Dir. of Third Party Payer
Joe Anne Hart, Chief Legislative Officer	Alexandra Abboud, Gov. Affairs Liaison

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|---|----------------|
| 1. <b>Call to Order</b>                 | Dr. Dave Boden |
| 2. <b>Recognition of Guests, if any</b> | Dr. Boden      |
| 3. <b>Opening Remarks</b>               | Dr. Boden      |

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|---|---|
| <p>4. <b>Meeting Participant Policy Reminder</b><br/>A. Conflict of Interest Statement – Page 3</p>   | <p>Dr. Boden</p>                                      |
| <p>5. <b>Adoption of Agenda</b></p>   | <p>Dr. Boden</p>                                      |
| <p>6. <b>BOD Meeting</b><br/>A. Agenda- Page 4<br/>B. Georgia Board of Dentistry Case- Page 7<br/>C. Executive Order on Promoting Competition in the American Economy- Page 12<br/>D. Council on Dental Hygiene Report- Page 28<br/>E. Petition for Variance or Waiver- Page 56<br/>F. Rule Discussion- Page 57<br/>G. AAO Letter (FYI)- Page 101</p> | <p>Dr. Boden<br/>Dr. Calderone<br/>Ms. Stoutamire</p> |
| <p>7. <b>Announcements</b></p>  | <p>Dr. Boden</p>                                      |
| <p>8. <b>Next GAC Meeting</b><br/>• Saturday, September 18, 2021<br/>In Person-Tallahassee</p>  | <p>Dr. Boden</p>                                      |
| <p>9. <b>Adjournment</b></p>  | <p>Dr. Boden</p>                                      |

## CONFLICTS OF INTEREST DISCLOSURE POLICY

For reference purposes at this meeting, all participants are advised of the FDA's policy governing the disclosure of conflicts of interest. This policy is codified as Resolution 92H-022, as adopted by the House of Delegates on January 9, 1993, and reads as follows:

Resolved, that individuals serving as delegates, alternate delegates, officers, trustees, alternate trustees, council or committee members shall, at all times, exercise diligent care and unbiased judgment in assuring that no detriment to the FDA results from conflicts between their personal or business interests and those interests of the FDA. And, be it further

Resolved, that agendas at all official meetings of FDA agencies contain a declaration of conflicts of interest at which time the presiding chairperson will ask all members of that body to express the conflict. And, be it further

Resolved, that if an individual believes that he or she or a member of his or her immediate family may have a conflict of interest, whether personal or business in nature, which pertains to an ownership, contractual, financial or fiduciary interest, then the individual shall promptly and fully disclose the possible conflict to the president of the association and/or chairperson of the body for which the individual serves. And, be it further

Resolved, that failure to disclose a material conflict of interest may be the basis for reconsideration of the question on a given issue according to parliamentary procedure at any further time.

**BOARD OF DENTISTRY  
GENERAL BUSINESS MEETING AGENDA  
August 13, 2021  
Sheraton Orlando North  
600 N. Lake Destiny Road  
Maitland, FL 32751  
(407) 660-9000  
7:30 A.M. ET**

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

**I. CALL TO ORDER/ROLL CALL**

**II. DISCIPLINARY PROCEEDINGS**

**A. Informal Hearings**

- i. Brian H. Gross, DDS, Case No. 2020-11200  
(PCP – Miro, Cherry, Morgan)

**B. Settlement Agreements**

- i. Akmal Ahmed, DDS, Case No. 2018-13620  
(PCP – Miro, Britten, Cabanzon)
- ii. Lloyd E. Beaufils, DDS, Case No. 2020-03485  
(PCP – Miro, Cherry, Morgan)
- iii. Renato Aves, DDS, Case No. 2018-11038  
(PCP – Miro, Cherry, Morgan)
- iv. Hector Briceno, DMD, Case No. 2018-05247  
(PCP – Miro, Morgan, Cherry)
- v. Harris L. Rittenberg, DMD, Case No. 2016-09153  
(PCP/1-11-19 – Fatmi, Morgan, White)  
(PCP/5-5-21 – Miro, Morgan, McCawley)
- vi. Vincent Dolce, DMD, Case No. 2019-18265  
(PCP – Miro, Morgan, Perdomo)
- vii. Jonathan Preble, DMD, Case No. 2018-11125  
(PCP – Miro, Morgan, Cherry)
- viii. Jorge O. Hernandez, DDS, Case No. 2018-07046  
(PCP – Fatmi, Britten, Morgan)

- ix. Jorge O. Hernandez, DDS, Case No. 2020-07741  
(PCP – Morgan, Cherry)

**C. Voluntary Relinquishment**

- i. Nicole Lynn Montalbano, DH, Case No. 2021-06826  
(PCP - Waived)
- ii. Aury Arroyo Lourenco, DH, Case No. 2020-31327  
(PCP – Miro, Cherry, Hill)
- iii. Ivan Graham, DDS, Case No. 2017-11704  
(PCP – Miro, Morgan, Calderone)

**III. PROSECUTION REPORT**

- A. Rose Garrison, Assistant General Counsel

**IV. RESPONDENT’S MOTION FOR RECONSIDERATION AND REHEARING**

- A. Tatyana Stepanchuk, DMD  
Case No. 2018-00406

**V. PETITION FOR MODIFICATION OF FINAL ORDER**

- A. Ivan Graham, DDS  
Case No. 2018-07212
- B. Jasen Genninger, DMD  
Case No. 2018-02149
- C. Lauren Kravitz, DDS  
Case No. 2015-26021
- D. Eric Schuetz, DDS  
Case No. 2013-10819

**VI. PETITION FOR VARIANCE OR WAIVER OF RULE**

- i. Michael Abdelmalik, DDS

**VII. REVIEW OF APPLICATIONS**

**A. Application for Dental License**

- i. Michael Kutsyk

**B. Application for General Sedation Permit**

- i. Matthew Green

**C. Application for License Reactivation**

- i. Charlotte Bonelli

## **VIII. REPORTS**

### **A. Board Counsel**

- i. Rules Report
- ii. JAPC Correspondence
- iii. Annual Regulatory Plan
- iv. Georgia Board of Dentistry Case
- v. Executive Order on Promoting Competition in the American Economy

### **B. Executive Director**

- i. Unlicensed Activity Liaison
- ii. Financial Reports

### **C. Chair**

### **D. Board Members**

- i. Ms. Hill
  1. Council on Dental Hygiene Report

### **E. Inspection Report**

- i. Ron Dilworth

## **IX. RULES DISCUSSION**

- i. Rule 64B5-12.013, F.A.C.
- ii. Disciplinary Guidelines
- iii. Fee Rule

## **X. DISCUSSION**

- A. CDCA Updates, Alex Vandiver, Chief Executive Officer
- B. Unlicensed Activity Presentation

## **XI. FOR YOUR INFORMATION**

- A. American Association of Orthodontists

## **XII. NEW BUSINESS**

- A. Licensure Ratification Lists
- B. Anesthesia Ratification List


## **XIII. OLD BUSINESS**


- A. Approval of Board Meeting Minutes – May 21, 2021
- B. Approval of Rule Hearing Minutes – May 21, 2021


# Full 11th Circ. Rejects Ga. Dental Board's Immunity Arguments

By **Bryan Koenig**

Law360 (July 20, 2021, 9:59 PM EDT) -- The full Eleventh Circuit ended a circuit split Tuesday over so-called state action safeguards protecting government agencies from antitrust suits, reversing a 1986 ruling giving agency members who were denied that protection immediate appellate rights, and sending members of Georgia's dental board back to face SmileDirectClub LLC's competition lawsuit.

The Eleventh Circuit had been the only circuit where private parties such as the Georgia Board of Dentistry's members could seek immediate, or interlocutory, appeal of district court rulings refusing to nix a lawsuit under the U.S. Supreme Court's 1943 [Parker v. Brown](#)  decision recognizing antitrust immunity for state agencies.

But the full court held unanimously Tuesday that the decision granting that right, and permitting parties to appeal before being hit with a "final" district court defeat — namely, [Commuter Transportation Systems v. Hillsborough County Aviation Authority](#)  — "incorrectly characterized Parker as creating an immunity from trial."

Parker safeguards, the court held in a decision penned by Circuit Judge Adalberto Jordan, are really meant only as a defense rather than a total immunity from being sued at all. Parker should only be read as addressing the scope of the Sherman Antitrust Act, holding that the law doesn't get to state action and not that it's barred from doing so, according to the opinion. From there, the judges cited the Supreme Court's 1994 admonition in [Digital Equipment Corp. v. Desktop Direct Inc.](#)  to view claims of an absolute right "with skepticism, if not a jaundiced eye,"

"Applying that skepticism here, we agree with the Fourth, Sixth, and Ninth Circuits that Parker did not arise from any special concerns that would result from having to go to trial, and that Parker protection is not lost if an immediate appeal is denied," Judge Jordan said.

The result is a decision Tuesday upholding a split circuit panel's **August 2020 opinion** rejecting the board members' appeal denying them state-action immunity. The court ordered an en banc rehearing of all its judges in December, but on Tuesday, every member held against the board members, finding they lack jurisdiction to hear the appeal. The main decision was backed by two separate concurring opinions.

SmileDirect is challenging a Georgia rule that requires dentists to supervise when digital photos are taken of prospective patients' teeth and gums in preparation for the company's clear teeth aligners.

Under SmileDirect's business model, images can be taken at its retail stores, which then transfer the collected information electronically to licensed dentists for review and creation of a treatment plan, a setup SmileDirect says allows it to offer aligners at a lower price.

The company contends Georgia's rule is intended to insulate the state's licensed dentists from competition in violation of antitrust laws. In trying to avoid facing that lawsuit, the board members, represented by Georgia Solicitor General Andrew Alan Pinson, **in February oral arguments**, had asserted that the rule received adequate oversight by the state's governor to qualify for state-action immunity.

On Tuesday, the court did not address the immunity question directly and instead focused entirely on whether the members have the right to seek immediate appeal under the "collateral order doctrine,"

which creates a route around the rule that only final judgments are usually appealable.

During oral arguments, Circuit Judge Andrew L. Brasher had cast doubt on the prospects for a unanimous decision, saying it has been law in the Eleventh Circuit for many decades that the court has jurisdiction over appeals like this, adding that he didn't see enough in the briefs to warrant getting rid of that precedent.

On Tuesday, however, Judge Brasher joined a concurring opinion penned by Circuit Judge William Pryor aimed at explaining why the Commuter Transportation Systems line of precedent is rightly being overruled, with the instant spat representing "the rare case in which overruling a circuit precedent is appropriate." The underlying precedent, Judge Pryor said, "misunderstands a defense to liability as an immunity from suit."

State-action immunity, according to the concurrence, is based on state action falling outside the ambit of the way the Sherman Act is currently written. But immunity from suit needs to be expressly granted.

"By contrast, a statutory omission establishes a mere defense to liability ... Our confusion about this distinction led us to conclude mistakenly that a non-final order based on Parker is immediately appealable under the collateral-order doctrine," Judge Pryor said. "Properly understood as a defense to liability, state-action immunity does not satisfy the requirements for immediate appealability."

Judge Pryor went on to warn of permitting "unnecessary interlocutory appeals" to tax the legal system.

A second concurrence, from Circuit Judge Gerald Bard Tjoflat, similarly sought to explain why Commuter should be overruled even though the lower court judge avoided deciding whether the Parker defense had been established by preferring to wait for more discovery. Judge Tjoflat wrote that "there's good reason to believe" immunity claims are different from liability defenses.

SmileDirect has also been battling restrictions imposed on its services **in Alabama** and **California**. It's also received backing in the instant case and the Alabama litigation from the U.S. Department of Justice and the Federal Trade Commission, which supported SmileDirect's contention that state action is about the reach of the Sherman Act, making it a merits question that cannot be snuffed out at an early stage of the litigation.

In Tuesday's main opinion, the appellate court closed with "a final observation" on the third requirement for weighing whether a ruling counts as a collateral order worthy of immediate appeal: "whether a right or claim can be vindicated adequately on appeal following final judgment."

In looking at the interests implicated by an end-run around the final judgment requirement, the court said that while Parker's interpretation of the Sherman Act is based in part in federalism, the high court's decision "does not reflect a value of sufficiently high order to satisfy the third condition of the collateral order doctrine."

In the face of the Supreme Court's 2006 **Will v. Hallock** decision holding that interlocutory appeals should only be granted when the rights implicated are extremely important to the public interest, the Eleventh Circuit found that Parker doesn't qualify.

"If the board members were correct, then the collateral order doctrine would potentially permit an immediate appeal of any pretrial order rejecting a claim by a state or its officials (or private parties acting in concert with a state) that a statute does not cover their conduct," Judge Jordan said. "The Supreme Court has never hinted at such an expansive view of the collateral order doctrine, and we decline to sanction it here."

"Effective review" is still available in upending a final judgment, according to the ruling, which noted that there are still some circumstances where rejected dismissal bids grounded in Parker could be grounds for appeal before a final decision.

SmileDirect chief legal officer and business affairs executive vice president Susan Greenspon Rammelt welcomed the ruling Tuesday.

"We are grateful for the support of the FTC and DOJ in this matter and look forward to a similar ruling in connection with the Alabama Dental Board's appeal of a lower court ruling in our favor," Rammelt said in a statement. "While we take no pleasure in disputes with dental boards, we cannot and will not let anticompetitive conduct interfere with our mission to democratize access to care."

A representative for the board did not immediately respond Tuesday to a request for comment.

SmileDirect is represented by Jeffrey S. Cashdan of King & Spalding LLP.

The dentistry board's members are represented by Georgia Solicitor General Andrew Alan Pinson.

The government is represented by Steven Mintz of the DOJ's Antitrust Division.

The case is SmileDirectClub LLC v. Battle et al., case number 19-12227, in the U.S. Court of Appeals for the Eleventh Circuit.

--Additional reporting by Matthew Perlman and Nadia Dreid. Editing by Andrew Cohen.

## 11th Circ. Tosses Ala. Dental Board's SmileDirect Appeal

By **J. Edward Moreno**


Law360 (July 29, 2021, 7:25 PM EDT) -- An Eleventh Circuit panel rejected an appeal from members of the Alabama dental board on Thursday, applying a standard set by a recent en banc ruling by the court in a similar case involving Georgia's dentistry board that determined the regulators aren't entitled to an early appeal.

The board, which is facing an antitrust suit by SmileDirectClub, has argued that as an arm of the state government it should be immune to such suits in the first place. The Eleventh Circuit determined it can't hear the appeal at this stage, sending the case back to the district court for discovery.

"We lack appellate jurisdiction over, and therefore grant SmileDirect's motion to dismiss, this interlocutory appeal," the panel said.

SmileDirectClub is a teledentistry platform that sends images taken by its employees to state-licensed dentists to decide whether the consumers might benefit from clear teeth-aligner therapy. The Alabama board, as well as similar boards in Georgia **and California**, have filed cease and desist orders to SmileDirectClub for not having a dentist on site while taking images of patients' mouths. SmileDirectClub sued the board, claiming the board conspired to block the company from the market.

The board filed a motion to dismiss and the district court tossed claims against the board itself under the state-action doctrine but kept claims against the six dentists and one dental hygienist who make up the board, which consist of Sherman Act antitrust claims and dominant commerce clause claims.

The board sought an interlocutory appeal in the Eleventh Circuit, claiming it is an arm of the government and therefore has immunity under the U.S. Supreme Court's 1943 **Parker v. Brown**  decision recognizing antitrust immunity for state agencies.

Last week, the full Eleventh Circuit made a decision in a **nearly identical case pending in Georgia**, ruling that Parker safeguards are really meant only as a defense rather than a total immunity from being sued at all. That ruling did not address whether that board had immunity, but whether it had the right to an immediate appeal.

The Eleventh Circuit applied the same standard to this case.

"This argument is foreclosed by binding precedent," the panel said. "After the board members filed their response to SmileDirect's motion, this court, sitting en banc, overruled the cases the board members had relied upon, squarely holding that district court orders denying Parker protection are not immediately appealable collateral orders."

The U.S. Department of Justice and the Federal Trade Commission supported SmileDirectClub in the appeal, arguing that the board members failed to show that they were being actively supervised by the state, which they argued is needed when a regulatory board is composed of industry participants.

Susan Greenspon Rammelt, SmileDirect chief legal officer and business affairs executive vice president, welcomed the Thursday ruling.

"SmileDirectClub is pleased with the appellate court's decision, and we are grateful for the  Amicus

support of the FTC and DOJ in this matter," Rammelt said in a statement. "For the past seven years, the company has been working to democratize access to premium, oral care and although it is always our preference to work with and educate dental boards and associations on the many benefits of our telehealth platform, we cannot and will not allow anti-competitive conduct to interfere with our mission."

U.S. Circuit Judges Charles Wilson and Jill A. Pryor and U.S. District Judge Timothy Corrigan sat on the panel for the Eleventh Circuit.

SmileDirectClub is represented by Matthew H. Lembke of Bradley Arant Boult Cummings LLP.

Alabama's dental examiners board is represented by Samuel H. Franklin, R. Ashby Pate and Logan T. Matthews of Lightfoot Franklin & White LLC.

The case is D. Leeds et al. v. Adolphus Jackson et al., case number 19-11502, in the U.S. Court of Appeals for the Eleventh Circuit.

--Additional reporting by Bryan Koenig. Editing by Orlando Lorenzo.

*Correction: This article has been updated to reflect that SmileDirectClub's dentists are state-licensed.*

## BRIEFING ROOM

# Executive Order on Promoting Competition in the American Economy

JULY 09, 2021 • PRESIDENTIAL ACTIONS

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to promote the interests of American workers, businesses, and consumers, it is hereby ordered as follows:

## Section 1. Policy.

A fair, open, and competitive marketplace has long been a cornerstone of the American economy, while excessive market concentration threatens basic economic liberties, democratic accountability, and the welfare of workers, farmers, small businesses, startups, and consumers.

The American promise of a broad and sustained prosperity depends on an open and competitive economy. For workers, a competitive marketplace creates more high-quality jobs and the economic freedom to switch jobs or negotiate a higher wage. For small businesses and farmers, it creates more choices among suppliers and major buyers, leading to more take-home income, which they can reinvest in their enterprises. For entrepreneurs, it provides space to experiment, innovate, and pursue the new ideas that have for centuries powered the American economy and improved our quality of life. And for consumers, it means more choices, better service, and lower prices.

Robust competition is critical to preserving America's role as the world's leading economy.

Yet over the last several decades, as industries have consolidated, competition has weakened in too many markets, denying Americans the benefits of an open economy and widening racial, income, and wealth inequality. Federal Government inaction has contributed to these problems, with workers, farmers, small businesses, and consumers paying the price.

Consolidation has increased the power of corporate employers, making it harder for workers to bargain for higher wages and better work conditions. Powerful companies require workers to sign non-compete agreements that restrict their ability to change jobs. And, while many occupational licenses are critical to increasing wages for workers and especially workers of color, some overly restrictive occupational licensing requirements can impede workers' ability to find jobs and to move between States.

Consolidation in the agricultural industry is making it too hard for small family farms to survive. Farmers are squeezed between concentrated market power in the agricultural input

industries — seed, fertilizer, feed, and equipment suppliers — and concentrated market power in the channels for selling agricultural products. As a result, farmers' share of the value of their agricultural products has decreased, and poultry farmers, hog farmers, cattle ranchers, and other agricultural workers struggle to retain autonomy and to make sustainable returns.

The American information technology sector has long been an engine of innovation and growth, but today a small number of dominant Internet platforms use their power to exclude market entrants, to extract monopoly profits, and to gather intimate personal information that they can exploit for their own advantage. Too many small businesses across the economy depend on those platforms and a few online marketplaces for their survival. And too many local newspapers have shuttered or downsized, in part due to the Internet platforms' dominance in advertising markets.

Americans are paying too much for prescription drugs and healthcare services — far more than the prices paid in other countries. Hospital consolidation has left many areas, particularly rural communities, with inadequate or more expensive healthcare options. And too often, patent and other laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs.

In the telecommunications sector, Americans likewise pay too much for broadband, cable television, and other communications services, in part because of a lack of adequate competition. In the financial-services sector, consumers pay steep and often hidden fees because of industry consolidation. Similarly, the global container shipping industry has consolidated into a small number of dominant foreign-owned lines and alliances, which can disadvantage American exporters.

The problem of economic consolidation now spans these sectors and many others, endangering our ability to rebuild and emerge from the coronavirus disease 2019 (COVID-19) pandemic with a vibrant, innovative, and growing economy. Meanwhile, the United States faces new challenges to its economic standing in the world, including unfair competitive pressures from foreign monopolies and firms that are state-owned or state-sponsored, or whose market power is directly supported by foreign governments.

We must act now to reverse these dangerous trends, which constrain the growth and dynamism of our economy, impair the creation of high-quality jobs, and threaten America's economic standing in the world.

This order affirms that it is the policy of my Administration to enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony — especially as these issues arise in labor markets, agricultural markets, Internet platform industries, healthcare markets (including insurance, hospital, and prescription drug markets), repair markets, and United States markets directly affected by foreign cartel activity.

It is also the policy of my Administration to enforce the antitrust laws to meet the challenges

posed by new industries and technologies, including the rise of the dominant Internet platforms, especially as they stem from serial mergers, the acquisition of nascent competitors, the aggregation of data, unfair competition in attention markets, the surveillance of users, and the presence of network effects.

Whereas decades of industry consolidation have often led to excessive market concentration, this order reaffirms that the United States retains the authority to challenge transactions whose previous consummation was in violation of the Sherman Antitrust Act (26 Stat. 209, 15 U.S.C. 1 *et seq.*) (Sherman Act), the Clayton Antitrust Act (Public Law 63-212, 38 Stat. 730, 15 U.S.C. 12 *et seq.*) (Clayton Act), or other laws. *See* 15 U.S.C. 18; *Standard Oil Co. v. United States*, 221 U.S. 1 (1911).

This order reasserts as United States policy that the answer to the rising power of foreign monopolies and cartels is not the tolerance of domestic monopolization, but rather the promotion of competition and innovation by firms small and large, at home and worldwide.

It is also the policy of my Administration to support aggressive legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms. It is further the policy of my Administration to support the enactment of a public health insurance option.

My Administration further reaffirms the policy stated in Executive Order 13725 of April 15, 2016 (Steps to Increase Competition and Better Inform Consumers and Workers to Support Continued Growth of the American Economy), and the Federal Government's commitment to the principles that led to the passage of the Sherman Act, the Clayton Act, the Packers and Stockyards Act, 1921 (Public Law 67-51, 42 Stat. 159, 7 U.S.C. 181 *et seq.*) (Packers and Stockyards Act), the Celler-Kefauver Antimerger Act (Public Law 81-899, 64 Stat. 1125), the Bank Merger Act (Public Law 86-463, 74 Stat. 129, 12 U.S.C. 1828), and the Telecommunications Act of 1996 (Public Law 104-104, 110 Stat. 56), among others.

## Sec. 2. The Statutory Basis of a Whole-of-Government Competition Policy.

(a) The antitrust laws, including the Sherman Act, the Clayton Act, and the Federal Trade Commission Act (Public Law 63-203, 38 Stat. 717, 15 U.S.C. 41 *et seq.*), are a first line of defense against the monopolization of the American economy.

(b) The antitrust laws reflect an underlying policy favoring competition that transcends those particular enactments. As the Supreme Court has stated, for instance, the Sherman Act “rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions.” *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958).

(c) Consistent with these broader policies, and in addition to the traditional antitrust laws, the Congress has also enacted industry-specific fair competition and anti-monopolization laws

that often provide additional protections. Such enactments include the Packers and Stockyards Act, the Federal Alcohol Administration Act (Public Law 74-401, 49 Stat. 977, 27 U.S.C. 201 *et seq.*), the Bank Merger Act, the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, 98 Stat. 1585), the Shipping Act of 1984 (Public Law 98-237, 98 Stat. 67, 46 U.S.C. 40101 *et seq.*) (Shipping Act), the ICC Termination Act of 1995 (Public Law 104-88, 109 Stat. 803), the Telecommunications Act of 1996, the Fairness to Contact Lens Consumers Act (Public Law 108-164, 117 Stat. 2024, 15 U.S.C. 7601 *et seq.*), and the Dodd-Frank Wall Street Reform and Consumer Protection Act (Public Law 111-203, 124 Stat. 1376) (Dodd-Frank Act).

(d) These statutes independently charge a number of executive departments and agencies (agencies) to protect conditions of fair competition in one or more ways, including by:

- (i) policing unfair, deceptive, and abusive business practices;
- (ii) resisting consolidation and promoting competition within industries through the independent oversight of mergers, acquisitions, and joint ventures;
- (iii) promulgating rules that promote competition, including the market entry of new competitors; and
- (iv) promoting market transparency through compelled disclosure of information.

(e) The agencies that administer such or similar authorities include the Department of the Treasury, the Department of Agriculture, the Department of Health and Human Services, the Department of Transportation, the Federal Reserve System, the Federal Trade Commission (FTC), the Securities and Exchange Commission, the Federal Deposit Insurance Corporation, the Federal Communications Commission, the Federal Maritime Commission, the Commodity Futures Trading Commission, the Federal Energy Regulatory Commission, the Consumer Financial Protection Bureau, and the Surface Transportation Board.

(f) Agencies can influence the conditions of competition through their exercise of regulatory authority or through the procurement process. *See* 41 U.S.C. 1705.

(g) This order recognizes that a whole-of-government approach is necessary to address overconcentration, monopolization, and unfair competition in the American economy. Such an approach is supported by existing statutory mandates. Agencies can and should further the polices set forth in section 1 of this order by, among other things, adopting pro-competitive regulations and approaches to procurement and spending, and by rescinding regulations that create unnecessary barriers to entry that stifle competition.

### Sec. 3. Agency Cooperation in Oversight, Investigation, and Remedies.

(a) The Congress frequently has created overlapping agency jurisdiction in the policing of anticompetitive conduct and the oversight of mergers. It is the policy of my Administration that, when agencies have overlapping jurisdiction, they should endeavor to cooperate fully in the exercise of their oversight authority, to benefit from the respective expertise of the agencies and to improve Government efficiency.

(b) Where there is overlapping jurisdiction over particular cases, conduct, transactions, or industries, agencies are encouraged to coordinate their efforts, as appropriate and consistent with applicable law, with respect to:

- (i) the investigation of conduct potentially harmful to competition;
- (ii) the oversight of proposed mergers, acquisitions, and joint ventures; and
- (iii) the design, execution, and oversight of remedies.

(c) The means of cooperation in cases of overlapping jurisdiction should include, as appropriate and consistent with applicable law:

- (i) sharing relevant information and industry data;
- (ii) in the case of major transactions, soliciting and giving significant consideration to the views of the Attorney General or the Chair of the FTC, as applicable; and
- (iii) cooperating with any concurrent Department of Justice or FTC oversight activities under the Sherman Act or Clayton Act.

(d) Nothing in subsections (a) through (c) of this section shall be construed to suggest that the statutory standard applied by an agency, or its independent assessment under that standard, should be displaced or substituted by the judgment of the Attorney General or the Chair of the FTC. When their views are solicited, the Attorney General and the Chair of the FTC are encouraged to provide a response to the agency in time for the agency to consider it in advance of any statutory deadline for agency action.

#### Sec. 4. The White House Competition Council.

(a) There is established a White House Competition Council (Council) within the Executive Office of the President.

(b) The Council shall coordinate, promote, and advance Federal Government efforts to address overconcentration, monopolization, and unfair competition in or directly affecting the American economy, including efforts to:

- (i) implement the administrative actions identified in this order;
- (ii) develop procedures and best practices for agency cooperation and coordination on matters of overlapping jurisdiction, as described in section 3 of this order;
- (iii) identify and advance any additional administrative actions necessary to further the policies set forth in section 1 of this order; and
- (iv) identify any potential legislative changes necessary to further the policies set forth in section 1 of this order.

(c) The Council shall work across agencies to provide a coordinated response to overconcentration, monopolization, and unfair competition in or directly affecting the American economy. The Council shall also work with each agency to ensure that agency operations are conducted in a manner that promotes fair competition, as appropriate and consistent with applicable law.

(d) The Council shall not discuss any current or anticipated enforcement actions. 16

(e) The Council shall be led by the Assistant to the President for Economic Policy and Director of the National Economic Council, who shall serve as Chair of the Council.

(f) In addition to the Chair, the Council shall consist of the following members:

- (i) the Secretary of the Treasury;
- (ii) the Secretary of Defense;
- (iii) the Attorney General;
- (iv) the Secretary of Agriculture;
- (v) the Secretary of Commerce;
- (vi) the Secretary of Labor;
- (vii) the Secretary of Health and Human Services;
- (viii) the Secretary of Transportation;
- (ix) the Administrator of the Office of Information and Regulatory Affairs; and
- (x) the heads of such other agencies and offices as the Chair may from time to time

invite to participate.

(g) The Chair shall invite the participation of the Chair of the FTC, the Chair of the Federal Communications Commission, the Chair of the Federal Maritime Commission, the Director of the Consumer Financial Protection Bureau, and the Chair of the Surface Transportation Board, to the extent consistent with their respective statutory authorities and obligations.

(h) Members of the Council shall designate, not later than 30 days after the date of this order, a senior official within their respective agency or office who shall coordinate with the Council and who shall be responsible for overseeing the agency's or office's efforts to address overconcentration, monopolization, and unfair competition. The Chair may coordinate subgroups consisting exclusively of Council members or their designees, as appropriate.

(i) The Council shall meet on a semi-annual basis unless the Chair determines that a meeting is unnecessary.

(j) Each agency shall bear its own expenses for participating in the Council.

#### Sec. 5. Further Agency Responsibilities.

(a) The heads of all agencies shall consider using their authorities to further the policies set forth in section 1 of this order, with particular attention to:

- (i) the influence of any of their respective regulations, particularly any licensing regulations, on concentration and competition in the industries under their jurisdiction; and
- (ii) the potential for their procurement or other spending to improve the competitiveness of small businesses and businesses with fair labor practices.

(b) The Attorney General, the Chair of the FTC, and the heads of other agencies with authority to enforce the Clayton Act are encouraged to enforce the antitrust laws fairly and vigorously.

(c) To address the consolidation of industry in many markets across the economy, as described in section 1 of this order, the Attorney General and the Chair of the FTC are 17

encouraged to review the horizontal and vertical merger guidelines and consider whether to revise those guidelines.

(d) To avoid the potential for anticompetitive extension of market power beyond the scope of granted patents, and to protect standard-setting processes from abuse, the Attorney General and the Secretary of Commerce are encouraged to consider whether to revise their position on the intersection of the intellectual property and antitrust laws, including by considering whether to revise the Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments issued jointly by the Department of Justice, the United States Patent and Trademark Office, and the National Institute of Standards and Technology on December 19, 2019.

(e) To ensure Americans have choices among financial institutions and to guard against excessive market power, the Attorney General, in consultation with the Chairman of the Board of Governors of the Federal Reserve System, the Chairperson of the Board of Directors of the Federal Deposit Insurance Corporation, and the Comptroller of the Currency, is encouraged to review current practices and adopt a plan, not later than 180 days after the date of this order, for the revitalization of merger oversight under the Bank Merger Act and the Bank Holding Company Act of 1956 (Public Law 84-511, 70 Stat. 133, 12 U.S.C. 1841 *et seq.*) that is in accordance with the factors enumerated in 12 U.S.C. 1828(c) and 1842(c).

(f) To better protect workers from wage collusion, the Attorney General and the Chair of the FTC are encouraged to consider whether to revise the Antitrust Guidance for Human Resource Professionals of October 2016.

(g) To address agreements that may unduly limit workers' ability to change jobs, the Chair of the FTC is encouraged to consider working with the rest of the Commission to exercise the FTC's statutory rulemaking authority under the Federal Trade Commission Act to curtail the unfair use of non-compete clauses and other clauses or agreements that may unfairly limit worker mobility.

(h) To address persistent and recurrent practices that inhibit competition, the Chair of the FTC, in the Chair's discretion, is also encouraged to consider working with the rest of the Commission to exercise the FTC's statutory rulemaking authority, as appropriate and consistent with applicable law, in areas such as:

(i) unfair data collection and surveillance practices that may damage competition, consumer autonomy, and consumer privacy;

(ii) unfair anticompetitive restrictions on third-party repair or self-repair of items, such as the restrictions imposed by powerful manufacturers that prevent farmers from repairing their own equipment;

(iii) unfair anticompetitive conduct or agreements in the prescription drug industries, such as agreements to delay the market entry of generic drugs or biosimilars;

(iv) unfair competition in major Internet marketplaces;

(v) unfair occupational licensing restrictions;

(vi) unfair tying practices or exclusionary practices in the brokerage or listing of real estate; and

(vii) any other unfair industry-specific practices that substantially inhibit competition.

(i) The Secretary of Agriculture shall:

(i) to address the unfair treatment of farmers and improve conditions of competition in the markets for their products, consider initiating a rulemaking or rulemakings under the Packers and Stockyards Act to strengthen the Department of Agriculture's regulations concerning unfair, unjustly discriminatory, or deceptive practices and undue or unreasonable preferences, advantages, prejudices, or disadvantages, with the purpose of furthering the vigorous implementation of the law established by the Congress in 1921 and fortified by amendments. In such rulemaking or rulemakings, the Secretary of Agriculture shall consider, among other things:

(A) providing clear rules that identify recurrent practices in the livestock, meat, and poultry industries that are unfair, unjustly discriminatory, or deceptive and therefore violate the Packers and Stockyards Act;

(B) reinforcing the long-standing Department of Agriculture interpretation that it is unnecessary under the Packers and Stockyards Act to demonstrate industry-wide harm to establish a violation of the Act and that the "unfair, unjustly discriminatory, or deceptive" treatment of one farmer, the giving to one farmer of an "undue or unreasonable preference or advantage," or the subjection of one farmer to an "undue or unreasonable prejudice or disadvantage in any respect" violates the Act;

(C) prohibiting unfair practices related to grower ranking systems – systems in which the poultry companies, contractors, or dealers exercise extraordinary control over numerous inputs that determine the amount farmers are paid and require farmers to assume the risk of factors outside their control, leaving them more economically vulnerable;

(D) updating the appropriate definitions or set of criteria, or application thereof, for undue or unreasonable preferences, advantages, prejudices, or disadvantages under the Packers and Stockyards Act; and

(E) adopting, to the greatest extent possible and as appropriate and consistent with applicable law, appropriate anti-retaliation protections, so that farmers may assert their rights without fear of retribution;

(ii) to ensure consumers have accurate, transparent labels that enable them to choose products made in the United States, consider initiating a rulemaking to define the conditions under which the labeling of meat products can bear voluntary statements indicating that the product is of United States origin, such as "Product of USA";

(iii) to ensure that farmers have greater opportunities to access markets and receive a fair return for their products, not later than 180 days after the date of this order, submit a report to the Chair of the White House Competition Council, with a plan to promote competition in the agricultural industries and to support value-added agriculture and alternative food

distribution systems through such means as:

(A) the creation or expansion of useful information for farmers, such as model contracts, to lower transaction costs and help farmers negotiate fair deals;

(B) measures to encourage improvements in transparency and standards so that consumers may choose to purchase products that support fair treatment of farmers and agricultural workers and sustainable agricultural practices;

(C) measures to enhance price discovery, increase transparency, and improve the functioning of the cattle and other livestock markets;

(D) enhanced tools, including any new legislative authorities needed, to protect whistleblowers, monitor agricultural markets, and enforce relevant laws;

(E) any investments or other support that could bolster competition within highly concentrated agricultural markets; and

(F) any other means that the Secretary of Agriculture deems appropriate;

(iv) to improve farmers' and smaller food processors' access to retail markets, not later than 300 days after the date of this order, in consultation with the Chair of the FTC, submit a report to the Chair of the White House Competition Council, on the effect of retail concentration and retailers' practices on the conditions of competition in the food industries, including any practices that may violate the Federal Trade Commission Act, the Robinson-Patman Act (Public Law 74-692, 49 Stat. 1526, 15 U.S.C. 13 *et seq.*), or other relevant laws, and on grants, loans, and other support that may enhance access to retail markets by local and regional food enterprises; and

(v) to help ensure that the intellectual property system, while incentivizing innovation, does not also unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act (*see* 35 U.S.C. 100 *et seq.* and 7 U.S.C. 2321 *et seq.*), in consultation with the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, submit a report to the Chair of the White House Competition Council, enumerating and describing any relevant concerns of the Department of Agriculture and strategies for addressing those concerns across intellectual property, antitrust, and other relevant laws.

(j) To protect the vibrancy of the American markets for beer, wine, and spirits, and to improve market access for smaller, independent, and new operations, the Secretary of the Treasury, in consultation with the Attorney General and the Chair of the FTC, not later than 120 days after the date of this order, shall submit a report to the Chair of the White House Competition Council, assessing the current market structure and conditions of competition, including an assessment of any threats to competition and barriers to new entrants, including:

(i) any unlawful trade practices in the beer, wine, and spirits markets, such as certain exclusionary, discriminatory, or anticompetitive distribution practices, that hinder smaller and independent businesses or new entrants from distributing their products;

(ii) patterns of consolidation in production, distribution, or retail beer, wine, and spirits

markets; and

(iii) any unnecessary trade practice regulations of matters such as bottle sizes, permitting, or labeling that may unnecessarily inhibit competition by increasing costs without serving any public health, informational, or tax purpose.

(k) To follow up on the foregoing assessment, the Secretary of the Treasury, through the Administrator of the Alcohol and Tobacco Tax and Trade Bureau, shall, not later than 240 days after the date of this order, consider:

(i) initiating a rulemaking to update the Alcohol and Tobacco Tax and Trade Bureau's trade practice regulations;

(ii) rescinding or revising any regulations of the beer, wine, and spirits industries that may unnecessarily inhibit competition; and

(iii) reducing any barriers that impede market access for smaller and independent brewers, winemakers, and distilleries.

(l) To promote competition, lower prices, and a vibrant and innovative telecommunications ecosystem, the Chair of the Federal Communications Commission is encouraged to work with the rest of the Commission, as appropriate and consistent with applicable law, to consider:

(i) adopting through appropriate rulemaking "Net Neutrality" rules similar to those previously adopted under title II of the Communications Act of 1934 (Public Law 73-416, 48 Stat. 1064, 47 U.S.C. 151 *et seq.*), as amended by the Telecommunications Act of 1996, in "Protecting and Promoting the Open Internet," 80 Fed. Reg. 19738 (Apr. 13, 2015);

(ii) conducting future spectrum auctions under rules that are designed to help avoid excessive concentration of spectrum license holdings in the United States, so as to prevent spectrum stockpiling, warehousing of spectrum by licensees, or the creation of barriers to entry, and to improve the conditions of competition in industries that depend upon radio spectrum, including mobile communications and radio-based broadband services;

(iii) providing support for the continued development and adoption of 5G Open Radio Access Network (O-RAN) protocols and software, continuing to attend meetings of voluntary and consensus-based standards development organizations, so as to promote or encourage a fair and representative standard-setting process, and undertaking any other measures that might promote increased openness, innovation, and competition in the markets for 5G equipment;

(iv) prohibiting unjust or unreasonable early termination fees for end-user communications contracts, enabling consumers to more easily switch providers;

(v) initiating a rulemaking that requires broadband service providers to display a broadband consumer label, such as that as described in the Public Notice of the Commission issued on April 4, 2016 (DA 16-357), so as to give consumers clear, concise, and accurate information regarding provider prices and fees, performance, and network practices;

(vi) initiating a rulemaking to require broadband service providers to regularly report broadband price and subscription rates to the Federal Communications Commission for the

purpose of disseminating that information to the public in a useful manner, to improve price transparency and market functioning; and

(vii) initiating a rulemaking to prevent landlords and cable and Internet service providers from inhibiting tenants' choices among providers.

(m) The Secretary of Transportation shall:

(i) to better protect consumers and improve competition, and as appropriate and consistent with applicable law:

(A) not later than 30 days after the date of this order, appoint or reappoint members of the Advisory Committee for Aviation Consumer Protection to ensure fair representation of consumers, State and local interests, airlines, and airports with respect to the evaluation of aviation consumer protection programs and convene a meeting of the Committee as soon as practicable;

(B) promote enhanced transparency and consumer safeguards, as appropriate and consistent with applicable law, including through potential rulemaking, enforcement actions, or guidance documents, with the aims of:

(1) enhancing consumer access to airline flight information so that consumers can more easily find a broader set of available flights, including by new or lesser known airlines; and

(2) ensuring that consumers are not exposed or subject to advertising, marketing, pricing, and charging of ancillary fees that may constitute an unfair or deceptive practice or an unfair method of competition;

(C) not later than 45 days after the date of this order, submit a report to the Chair of the White House Competition Council, on the progress of the Department of Transportation's investigatory and enforcement activities to address the failure of airlines to provide timely refunds for flights cancelled as a result of the COVID-19 pandemic;

(D) not later than 45 days after the date of this order, publish for notice and comment a proposed rule requiring airlines to refund baggage fees when a passenger's luggage is substantially delayed and other ancillary fees when passengers pay for a service that is not provided;

(E) not later than 60 days after the date of this order, start development of proposed amendments to the Department of Transportation's definitions of "unfair" and "deceptive" in 49 U.S.C. 41712; and

(F) not later than 90 days after the date of this order, consider initiating a rulemaking to ensure that consumers have ancillary fee information, including "baggage fees," "change fees," and "cancellation fees," at the time of ticket purchase;

(ii) to provide consumers with more flight options at better prices and with improved service, and to extend opportunities for competition and market entry as the industry evolves:

(A) not later than 30 days after the date of this order, convene a working group within the Department of Transportation to evaluate the effectiveness of existing commercial aviation

programs, consumer protections, and rules of the Federal Aviation Administration;

(B) consult with the Attorney General regarding means of enhancing effective coordination between the Department of Justice and the Department of Transportation to ensure competition in air transportation and the ability of new entrants to gain access; and

(C) consider measures to support airport development and increased capacity and improve airport congestion management, gate access, implementation of airport competition plans pursuant to 49 U.S.C. 47106(f), and “slot” administration;

(iii) given the emergence of new aerospace-based transportation technologies, such as low-altitude unmanned aircraft system deliveries, advanced air mobility, and high-altitude long endurance operations, that have great potential for American travelers and consumers, yet also the danger of early monopolization or new air traffic control problems, ensure that the Department of Transportation takes action with respect to these technologies to:

(A) facilitate innovation that fosters United States market leadership and market entry to promote competition and economic opportunity and to resist monopolization, while also ensuring safety, providing security and privacy, protecting the environment, and promoting equity; and

(B) provide vigilant oversight over market participants.

(n) To further competition in the rail industry and to provide accessible remedies for shippers, the Chair of the Surface Transportation Board (Chair) is encouraged to work with the rest of the Board to:

(i) consider commencing or continuing a rulemaking to strengthen regulations pertaining to reciprocal switching agreements pursuant to 49 U.S.C. 11102(c), if the Chair determines such rulemaking to be in the public interest or necessary to provide competitive rail service;

(ii) consider rulemakings pertaining to any other relevant matter of competitive access, including bottleneck rates, interchange commitments, or other matters, consistent with the policies set forth in section 1 of this order;

(iii) to ensure that passenger rail service is not subject to unwarranted delays and interruptions in service due to host railroads’ failure to comply with the required preference for passenger rail, vigorously enforce new on-time performance requirements adopted pursuant to the Passenger Rail Investment and Improvement Act of 2008 (Public Law 110-423, 122 Stat. 4907) that will take effect on July 1, 2021, and further the work of the passenger rail working group formed to ensure that the Surface Transportation Board will fully meet its obligations; and

(iv) in the process of determining whether a merger, acquisition, or other transaction involving rail carriers is consistent with the public interest under 49 U.S.C. 11323-25, consider a carrier’s fulfillment of its responsibilities under 49 U.S.C. 24308 (relating to Amtrak’s statutory rights).

(o) The Chair of the Federal Maritime Commission is encouraged to work with the rest of

the Commission to:

(i) vigorously enforce the prohibition of unjust and unreasonable practices in the context of detention and demurrage pursuant to the Shipping Act, as clarified in “Interpretive Rule on Demurrage and Detention Under the Shipping Act,” 85 Fed. Reg. 29638 (May 18, 2020);

(ii) request from the National Shipper Advisory Committee recommendations for improving detention and demurrage practices and enforcement of related Shipping Act prohibitions; and

(iii) consider further rulemaking to improve detention and demurrage practices and enforcement of related Shipping Act prohibitions.

(p) The Secretary of Health and Human Services shall:

(i) to promote the wide availability of low-cost hearing aids, not later than 120 days after the date of this order, publish for notice and comment a proposed rule on over-the-counter hearing-aids, as called for by section 709 of the FDA Reauthorization Act of 2017 (Public Law 115-52, 131 Stat. 1005);

(ii) support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by the No Surprises Act (Public Law 116-260, 134 Stat. 2758) or any other statutes;

(iii) to ensure that Americans can choose health insurance plans that meet their needs and compare plan offerings, implement standardized options in the national Health Insurance Marketplace and any other appropriate mechanisms to improve competition and consumer choice;

(iv) not later than 45 days after the date of this order, submit a report to the Assistant to the President for Domestic Policy and Director of the Domestic Policy Council and to the Chair of the White House Competition Council, with a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging;

(v) to lower the prices of and improve access to prescription drugs and biologics, continue to promote generic drug and biosimilar competition, as contemplated by the Drug Competition Action Plan of 2017 and Biosimilar Action Plan of 2018 of the Food and Drug Administration (FDA), including by:

(A) continuing to clarify and improve the approval framework for generic drugs and biosimilars to make generic drug and biosimilar approval more transparent, efficient, and predictable, including improving and clarifying the standards for interchangeability of biological products;

(B) as authorized by the Advancing Education on Biosimilars Act of 2021 (Public Law 117-8, 135 Stat. 254, 42 U.S.C. 263-1), supporting biosimilar product adoption by providing effective educational materials and communications to improve understanding of biosimilar and interchangeable products among healthcare providers, patients, and caregivers; 24

(C) to facilitate the development and approval of biosimilar and interchangeable products, continuing to update the FDA's biologics regulations to clarify existing requirements and procedures related to the review and submission of Biologics License Applications by advancing the "Biologics Regulation Modernization" rulemaking (RIN 0910-AI14); and

(D) with the Chair of the FTC, identifying and addressing any efforts to impede generic drug and biosimilar competition, including but not limited to false, misleading, or otherwise deceptive statements about generic drug and biosimilar products and their safety or effectiveness;

(vi) to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law, not later than 45 days after the date of this order, through the Commissioner of Food and Drugs, write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA;

(vii) to support the market entry of lower-cost generic drugs and biosimilars, continue the implementation of the law widely known as the CREATES Act of 2019 (Public Law 116-94, 133 Stat. 3130), by:

(A) promptly issuing Covered Product Authorizations (CPAs) to assist product developers with obtaining brand-drug samples; and

(B) issuing guidance to provide additional information for industry about CPAs; and

(viii) through the Administrator of the Centers for Medicare and Medicaid Services, prepare for Medicare and Medicaid coverage of interchangeable biological products, and for payment models to support increased utilization of generic drugs and biosimilars.

(q) To reduce the cost of covered products to the American consumer without imposing additional risk to public health and safety, the Commissioner of Food and Drugs shall work with States and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066), and the FDA's implementing regulations.

(r) The Secretary of Commerce shall:

(i) acting through the Director of the National Institute of Standards and Technology (NIST), consider initiating a rulemaking to require agencies to report to NIST, on an annual basis, their contractors' utilization activities, as reported to the agencies under 35 U.S.C. 202(c) (5);

(ii) acting through the Director of NIST, consistent with the policies set forth in section 1 of this order, consider not finalizing any provisions on march-in rights and product pricing in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," 86 Fed. Reg. 35 (Jan. 4, 2021); and

(iii) not later than 1 year after the date of this order, in consultation with the Attorney General and the Chair of the Federal Trade Commission, conduct a study, including by 25

conducting an open and transparent stakeholder consultation process, of the mobile application ecosystem, and submit a report to the Chair of the White House Competition Council, regarding findings and recommendations for improving competition, reducing barriers to entry, and maximizing user benefit with respect to the ecosystem.

(s) The Secretary of Defense shall:

(i) ensure that the Department of Defense's assessment of the economic forces and structures shaping the capacity of the national security innovation base pursuant to section 889(a) and (b) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283, 134 Stat. 3388) is consistent with the policy set forth in section 1 of this order;

(ii) not later than 180 days after the date of this order, submit to the Chair of the White House Competition Council, a review of the state of competition within the defense industrial base, including areas where a lack of competition may be of concern and any recommendations for improving the solicitation process, consistent with the goal of the Competition in Contracting Act of 1984 (Public Law 98-369, 98 Stat. 1175); and

(iii) not later than 180 days after the date of this order, submit a report to the Chair of the White House Competition Council, on a plan for avoiding contract terms in procurement agreements that make it challenging or impossible for the Department of Defense or service members to repair their own equipment, particularly in the field.

(t) The Director of the Consumer Financial Protection Bureau, consistent with the pro-competition objectives stated in section 1021 of the Dodd-Frank Act, is encouraged to consider:

(i) commencing or continuing a rulemaking under section 1033 of the Dodd-Frank Act to facilitate the portability of consumer financial transaction data so consumers can more easily switch financial institutions and use new, innovative financial products; and

(ii) enforcing the prohibition on unfair, deceptive, or abusive acts or practices in consumer financial products or services pursuant to section 1031 of the Dodd-Frank Act so as to ensure that actors engaged in unlawful activities do not distort the proper functioning of the competitive process or obtain an unfair advantage over competitors who follow the law.

(u) The Director of the Office of Management and Budget, through the Administrator of the Office of Information and Regulatory Affairs, shall incorporate into its recommendations for modernizing and improving regulatory review required by my Memorandum of January 20, 2021 (Modernizing Regulatory Review), the policies set forth in section 1 of this order, including consideration of whether the effects on competition and the potential for creation of barriers to entry should be included in regulatory impact analyses.

(v) The Secretary of the Treasury shall:

(i) direct the Office of Economic Policy, in consultation with the Attorney General, the Secretary of Labor, and the Chair of the FTC, to submit a report to the Chair of the White House Competition Council, not later than 180 days after the date of this order, on the effects of lack of competition on labor markets; and

(ii) submit a report to the Chair of the White House Competition Council, not later than 270 days after the date of this order, assessing the effects on competition of large technology firms' and other non-bank companies' entry into consumer finance markets.

Sec. 6. General Provisions.

(a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Where not already specified, independent agencies are encouraged to comply with the requirements of this order.

(c) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

JOSEPH R. BIDEN JR.

THE WHITE HOUSE,  
July 9, 2021.



Azena Medical, LLC  
Lindsay Tilton  
Regulatory & Quality Affairs Manager  
3021 Citrus Circle Ste 180  
Walnut Creek, California 94598

Re: K192617  
Trade/Device Name: Gemini 810+980 Diode Laser  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In  
Dermatology  
Regulatory Class: Class II  
Product Code: GEX, ILY  
Dated: January 2, 2020  
Received: January 21, 2020

Dear Lindsay Tilton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Mavadia-Shukla, Ph.D.  
Acting Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K192617

Device Name  
Gemini 810 +980 Diode Laser

### Indications for Use (Describe)

#### Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Treatment of aphthous ulcers.
- Vestibuloplasty
- Tissue retraction for impression
- Lesion (tumor) removal.

#### Laser Periodontal Procedures.

- Laser soft tissue curettage.
- Laser removal of diseased, Infected, Inflamed and necrosed soft tissue within the periodontal pocket.
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation

#### Pain therapy

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and

stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain, the temporary increase in local blood circulation; the temporary relaxation of muscle.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services  
Food and Drug Administration  
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**Section 5**  
**510(k) Summary**

**510(k) Summary of Safety and Effectiveness**

**Traditional 510(k) Premarket Notification**

**Submitter:**

Azena Medical, LLC  
3021 Citrus Cir Ste 180  
Walnut Creek, CA 94598

Phone: (800) 466 - 5273

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**Regulatory Authority:**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92.

**1. Submitter's name, address, telephone number, contact person, and date summary prepared:**

**Submitter:** Azena Medical, LLC  
3021 Citrus Cir Ste 180  
Walnut Creek, CA 94598

**Contact Person:** Lindsay Tilton  
Regulatory & Quality Affairs Manager  
Phone: 800-466-5273  
Email: ltilton@azenamedical.com

**Date of Preparation:** February 12, 2020

**2. Name of device, including the trade name and classification name:**

**Trade Name:** Gemini 810 + 980 Diode Laser

**Common Name(s):** Powered laser surgical instrument, Infrared lamp

**Classification Name(s):** Laser surgical instrument for use in general and plastic surgery and in dermatology; and infrared lamp

**Regulation Number:** **21 CFR 878.4810**

**Device Class:** Class II for all requested indications

**Product Code:** GEX, ILY

**Classification Panel:** General and Plastic Surgery & Others  
Physical Medicine Therapeutic Devices

**3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

**Primary Predicate Device:**

**Company:** Azena Medical, LLC  
**Device:** Elumi 810+980 Soft Tissue Laser  
**510(k):** K152032  
**Date Cleared:** September 16, 2015

**Reference Predicate Device:**

**Company:** Biolase Technology, Inc.  
**Device:** Epic 10  
**510(k):** K121286  
**Date Cleared:** September 28, 2012

**4. A description of the device that is the subject of the 510(k), including an explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

Gemini is an 810nm + 980nm soft tissue laser is intended for the incision, excision, ablation, vaporization, hemostasis and treatment of oral soft tissue and for pain relief using photobiomodulation. The Gemini laser operates at a wavelength of 810nm  $\pm$  10nm or at 980  $\pm$  10nm or a combination of both 810nm + 980nm wavelengths, with a maximum average power of 2 watts  $\pm$  20% and maximum peak pulse power of 20 watts  $\pm$  20% when in dual wavelength mode. The dual wavelength diode laser radiation is delivered through a flexible optical fiber and the Photobiomodulation (PBM) Adapter. Infrared laser energy is emitted from the fiber tips and the PBM Adapter when the wireless footswitch is depressed. The laser diodes are directly coupled to the flexible fiber optic cable that connects the laser unit to the surgical hand piece and to the disposable fiber tip and PBM Adapter that emits the energy to the target area. The laser diodes can simultaneously emit energy when Gemini is set to dual wavelength mode.

The Gemini unit comprises of six main assemblies: a Laser unit, a flexible fiber optic delivery system tethered to an anodized aluminum hand piece, disposable single-use fiber tips, PBM Adapter with spacers, a wireless footswitch, and an auxiliary power supply. The system also contains a 5mW 650nm laser diode coupled to the same fiber optic cable to produce the red aiming light. The laser system is contained within a compact lightweight impact resistant molded plastic housing that contains a laser diode assembly, a laser power controller PCB, an Electroluminescent Display connected to an interface PCB, a touch sensitive selection panel with status lights, and a rechargeable Lithium Battery. The hand piece used by the practitioner consists of an anodized aluminum cylindrical body which encloses the optics used to transfer

the laser energy to the single-use fiber tips and the PBM Adapter. The LED illumination system for lighting the work area will be off for PBM Adapter.

The laser's visible light is designed to aid the clinician in aiming the tip of the delivery fiber into the target tissue. Additionally, a bright white light from the LEDs in the hand piece illuminates target work area during procedures through the translucent disposable laser tips.

The PBM Adapter is an accessory attachment to the Gemini laser system to increase the spot size of the laser beam, allowing the Gemini Laser to provide near-infrared laser energy to a tissue surface for the purpose of photobiomodulation. Affected muscles and/or joints must be exposed to an adequate level of laser energy over a period of time to provide effective results. The spot size of the PBM Adapter is 25 mm. The PBM Adapter operates at  $810\text{nm} \pm 10\text{nm}$  wavelength with a maximum average power of  $1\text{ watt} \pm 20\%$ .

A PBM spacer is attached to the PBM Adapter. The spacer is a single-use disposable piece designed to ensure proper working distance to target tissues and limit the risk of cross contamination between patients. The PBM Adapter is designed to only work with the Gemini Laser System.

Gemini 810 + 980 Diode Laser utilizes non-volatile, preprogrammed firmware that cannot be modified by the user. During the development process, requirements are met, hazards are evaluated and mitigated for the safety of the patient and /or the operator and the firmware. It does not capture any data related to patients. The Gemini software focuses on the functional and technical design for the Gemini laser. This includes the graphical user interface (GUI), the control of the laser drivers, sound, tip illumination and aiming light.

## **5. INDICATIONS FOR USE:**

*The indications for use are identical to those of the previously cleared Predicate Device, ELUMI 810+980 Soft Tissue Laser and similar to the Epic 10 Laser. The only difference with the ELUMI 810+980 Soft Tissue Laser is that device is not cleared for the indication of Pain Management.*

### Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions

- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Treatment of aphthous ulcers.
- Vestibuloplasty
- Tissue retraction for impression
- Lesion (tumor) removal.

#### Laser Periodontal Procedures.

- Laser soft tissue curettage.
- Laser removal of diseased, Infected, Inflamed and necrosed soft tissue within the periodontal pocket.
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

- Reduction of bacterial level (decontamination) and inflammation

#### Pain therapy

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain, the temporary increase in local blood circulation; the temporary relaxation of muscle.

#### 6. **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

	<b>Gemini 810 + 980 Diode Laser</b>	<b>Elumi Soft Tissue Laser Primary Predicate</b>	<b>Epic 10 Reference predicate device</b>
<b>Laser Classification</b>	IV (4)	IV (4)	IV (4)
<b>Type of Laser</b>	Diode Laser	Diode Laser	Diode Laser
<b>Laser Medium</b>	GaAIAs	GaAIAs	InGaAsP
<b>Product Code(s)</b>	GEX; ILY	GEX	GEX; ILY
<b>Wavelength</b>	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	940 ± 10 nm
<b>Average Output Power</b>	Adjustable 0.1 - 2 Watts	Adjustable 0.1 - 2 Watts	Adjustable 0.1 – 10.0 Watts
<b>Max Peak Output Power</b>	20 Watts	20 Watts	10 watts
<b>Increments of Power Available</b>	0.1 Watts	0.1 Watts	0.1 Watts
<b>Operating Voltage</b>	100-240 VAC	100-240 VAC	100-240 VAC
<b>Current Frequency</b>	50-60 HZ	50-60 HZ	50-60 Hz
<b>Operation Mode</b>	Pulsed	Pulsed	Pulsed, Continuous
<b>Pulse Type</b>	Gated	Gated	Gated
<b>Battery</b>	Lithium Ion Rechargeable	Lithium Ion Rechargeable	Lithium Ion Rechargeable
<b>Delivery System</b>	Quartz glass fiber & tip	Quartz glass fiber & tip	Quartz glass fiber & tip

<b>Fiber/Tip Diameter</b>	400 µm flexible fiber optic cable	400 µm flexible fiber optic cable	200 µm, 300 µm, 400 µm flexible fiber Optic Cable
<b>Spot Size at Target</b>	400 µm diameter; 25mm PBM Adapter	400 µm diameter	200 µm, 300 µm, 400 µm diameter; adjustable 15-30 mm Pain management handpiece
<b>Fiber Aiming Beam</b>	5mW laser diode, 650nm, Class 1	5mW laser diode, 650nm, Class 1	Laser Diode max. 1mW, 635 ± 10 nm, class 1
<b>Activation Means</b>	Wireless Foot Switch, with electronic access key	Wireless Foot Switch, with electronic access key	Wireless Foot Switch, with electronic access key

The Gemini 810 + 980 Diode Laser has the equivalent indications for use and technological characteristics as that of the Predicate Device with the exception of pain management, which is indicated in the reference predicate device indications for use. The difference that exist between the Gemini 810 + 980 Diode Laser and the Predicate Devices do not alter the fundamental scientific technology of the device, and most importantly have no effect on the ability of either laser system to output laser energy at safe and effective levels of average power.

## 7. **Performance Data:**

The Gemini 810 + 980 Diode Laser was tested in accordance, and found to be in compliance, with the following national and international standards:

- 21 CFR 1040.10 & 1040.11 except for deviations pursuant to laser notice 50 dated June 24, 2007
- IEC 60601-2-22 Edition 3.1 2012-10
- IEC 60825-1Edition 2.0 2007-03
- AAMI/ANSI ES60601-1:2005/ (R) 2012 and A1:2012
- IEC 60601-1-2 Edition 4.0 2014-02
- AAMI/ANSI ST81:2004/(R)2016
- AAMI/ANSI ST79:2017
- AAMI/ANSI/ISO 17665-1:2006/( R)2013
- AAMI/ANSI/ISO 17665-2:2009-01-15
- AAMI/ANSI/ISO 10993-5:2009/( R)2014

## **Cleaning and Sterilization**

Cleaning validation was conducted according to FDA Reprocessing Guidance. The recovery method for the Anodized Aluminum Surgical Hand Piece with Fiber Connector achieved 78.5% and 77.6% recoveries for protein and hemoglobin respectively. All cleaned devices for the Anodized Aluminum Surgical Hand Piece with Fiber Connector were found to contain < 5.4 µg/cm<sup>2</sup> and < 1.6 µg/cm<sup>2</sup> for protein and hemoglobin respectively. The cleaning procedure is validated for the reprocessing of the Anodized Aluminum Surgical Hand Piece with Fiber Connector.

Sterilization validation was conducted to validate a fifteen -minute gravity steam sterilization cycle at 135°C for the Anodized Aluminum Hand Piece Shell. There was no growth of the biological indicators that had been exposed to steam with the test article. The verified half cycle indicates that a full gravity cycle of not less than 15 minutes at 135°C is capable of a 12 log reduction and will provide a 10<sup>-6</sup> sterility assurance level of a worst case population. The gravity cycle of 135°C at 15 minutes is validated for the Anodized Aluminum Hand Piece Shell.

### **Electrical Safety and EMC Testing**

Testing to verify the conformity of the Gemini 810+980 Diode Laser, with the requirements of IEC 60601-1: (*Medical electrical equipment Part 1: General requirements for basic safety and essential performance*).

Testing to verify the conformity of the Gemini 810+980 Diode Laser with the requirements of IEC 60601-1 -2: (*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility*).

Testing to verify the conformity of the Gemini 810+980 Diode Laser to IEC 60825-1 (*Safety of laser products – Part 1: Equipment classification and requirements*).

Testing to verify the performance of Gemini 810+980 Diode Laser according to IEC 60601-2-22: (*Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment*).

### **Software**

Validation of the device's software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*).

### **Non-Clinical**

Bench testing was also conducted on the Gemini 810+980 Diode Laser and found that Gemini meets the features and functions as identified in 21 CFR 1040.10.

Comparative bench testing was conducted on Gemini 810+980 Diode Laser using the new PBM Adapter in comparison with Biolase Epic 10 with pain therapy handpiece to ensure equivalence in pain management laser energy output, therefore ensuring new indication for use equivalence. The testing resulted in similar power density and spot size. It was found that the Gemini with PBM Adapter is substantially equivalent to Epic 10 with pain therapy handpiece and laser energy output.

Skin temperature testing was also conducted. The mechanisms of action for ILY product code, lamp, infrared, therapeutic heating, is to raise the skin temperature to 40-45 degrees Celsius and maintain for a minimum of 10 minutes. It was determined that the Gemini 810+980 Diode

K192617

Laser with PBM Adapter increases topical heat at the tissues level to 40 degrees Celsius and can maintain this temperature for a minimum of 10 minutes during treatment.

This performance data, along with conformity to the recognized national and international standards cited above, demonstrates that the Gemini 810 + 980 Diode Laser supports and performs as well as or better than its predicate devices.

No clinical data was submitted for this Traditional 510(k).

## **8. Conclusions:**

The Gemini 810 + 980 Diode Laser has the equivalent indications for use and technological characteristics as that of the Predicate Device with the exception of the pain management indication. The minor differences in indications do not raise any new questions of safety or effectiveness. The original indications in Gemini were already cleared through a prior 510(k) (K152032). The minor technological differences that exist between the Gemini 810 + 980 Diode Laser and its predicate device do not alter the fundamental scientific technology of the device and raise no new questions of safety or effectiveness. Performance data demonstrates that the Gemini 810 + 980 Diode Laser is as safe and as effective as its Predicate Device. The addition of the pain management indication is equivalent to the reference device Biolase's Epic 10. Comparative bench testing shows that the Gemini laser is substantially equivalent when it comes to the pain management function against the Epic 10



Biolase, Inc  
Alicia Mszyca  
Director, Regulatory Affairs  
4 Cromwell  
Irvine, California 92618

Re: K193486  
Trade/Device Name: Epic 980  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In  
Dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: December 13, 2019  
Received: December 17, 2019

Dear Alicia Mszyca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Mavadia-Shukla, Ph.D.  
Acting Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K193486

Device Name  
Epic 980

### Indications for Use (Describe)

#### Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft-tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty
- Tissue retraction for impression
- Laser soft-tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Lesion (tumor) removal
- Removal of hyperplastic tissues
- Laser assisted flap surgery
- Removal of granulation tissue

#### Whitening

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

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Pain Therapy

• Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

---

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510(k) SUMMARY

**I. SUBMITTER**

Biolase, Inc.  
4 Cromwell  
Irvine, CA 92618 USA  
Tel: (949) 226-8471  
Fax: (949) 273-6688  
Contact Person: Alicia Mszyca  
Date Prepared: December 13, 2019

**II. DEVICE**

Name of Device: **Epic 980**  
Common Name: Dental Diode Laser  
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)  
Device Class: II  
Product Code: GEX

**III. PREDICATE DEVICES**

Epic 980 (K192430)  
QuickLase 980, 810 & Dual (K100474)  
SIROLase Advance (K103753)  
Elumi 810+980 (K152032)  
Curative980 Diode Laser (K082445)

**IV. DEVICE DESCRIPTION**

The Epic 980 diode laser is a surgical and therapeutic device designated for a wide variety of oral soft-tissue procedures and dental whitening as well as for use in providing a temporary relief of minor pain.

The device uses a solid-state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a handpiece that emits the energy to the treatment site.

The laser is comprised of a base console, a wireless footswitch which activates the laser and a detachable delivery system consisting of a fiber optic cable, surgical handpiece and single-use disposable tips designed and optimized for different applications.

## V. INDICATIONS FOR USE STATEMENT

### Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft-tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty
- Tissue retraction for impression
- Laser soft-tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft-tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Lesion (tumor) removal
- Removal of hyperplastic tissues
- Laser assisted flap surgery
- Removal of granulation tissue

## Whitening

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

## Pain Therapy

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Epic 980 subject device is the same as Epic 980 (K192430) except for the expanded indications for use already cleared for devices: *Quicklase 810, 980, Dual +* (K100474) by QuickLase Limited, *SIROLaser Advance* (K103753) by Sirona, *Elumi 810 + 980* (K152032) by Azena Medical, LLC and *Curative980* (K082445) by OroScience, Inc.

The Epic 980 shares the same technological characteristic as the predicate devices including:

- the same laser source: solid state diode producing invisible infrared energy
- the same wavelength: 980nm
- the same intended use: incision, excision, vaporization, ablation and coagulation of oral soft tissue
- the same indications for use
- the same patient-contacting components: glass fiber used in contact and non-contact mode the same use environment
- the same tissue type and application regimen
- the same principle of operation and emission mode: continuous wave, pulsed or both the same control mechanism
- similar design consisting of software-operated portable laser unit, initiated by a footswitch similar delivery system comprising of an optical fiber, handpiece and single use disposable tips
- the same human factors of user interface

Although some parameters such as maximum power output, power density, pulse rate differ among the devices, these differences do not result in a significantly different clinical performance since the settings and used for the expanded indications as well as the treatment regimen are essentially the same. Therefore, the consolidation of clinical applications creates no new risks or safety concerns.

# BIOLASE

Comparison of the technological characteristics, intended use, indications for use of the Epic 980 subject and predicate devices:

	Subject Device	Predicate Devices				Reference Device
Specification	Biolase Inc. Epic 980	Biolase, Inc. <b>Epic 980</b> <b>(K192430)</b>	QuickLase Limited <b>QuickLase 980, 810</b> <b>and Dual+</b> <b>(K100474)</b>	Sirona <b>SIROLaser Advance</b> <b>(K103753)</b>	Azena Medical, LLC <b>Elumi 810 + 980</b> <b>(K152032)</b>	OroScience, Inc. <b>Curative980 Diode</b> <b>Laser (K082445)</b>
Laser medium	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser	Solid state diode laser
Wavelength	980 ±10 nm	980 ±10 nm	980 ± 10 nm, or 810 ± 10nm, or dual (810+980)	970 ± 15nm	980 ±10 nm, or 810 ± 10nm, or dual (810+980)	980 ± 10 nm
	The devices cleared under K100474 and K152032 operate in 3 different wavelengths: 980nm alone, 810nm alone and dual (810+980 nm). Biolase is claiming equivalence to the 980 nm version only. Therefore, substantially equivalent.					
Operating modes	Continuous, pulsed	Continuous, pulsed	Continuous, pulsed	Continuous, chopped(pulsed), peak pulse	Pulsed	Continuous, pulsed
Max Power (CW)	10 W	10 W	10W	7W	2W	10 W
	Although Epic 980 is capable of reaching 10W max power, the power settings used for all expanded indications do not exceed 1W, which is sufficient for effective performance and also falls under the maximum power of devices cleared under K103753 and K152032. Therefore, substantially equivalent.					
Max Peak Power	10 W	10 W	10W @980, or 10W @810, or 20W @ dual	14W	10W @980, or 10W @810, or 20W @ dual	unknown
Repetition rate (Frequency)	Up to 20 kHz	Up to 20 kHz	Up to 20 kHz	Up to 20 kHz	50 Hz	unknown

Biolase, Inc.  
510(k) - Epic 980

Pulse duration	0.01 - 20 ms	0.01 - 20 ms	50, 30, 10ms	0.01 – 0.99 s	variable	unknown
Spot size tips	200 – 400 $\mu\text{m}$	200 – 400 $\mu\text{m}$	400 $\mu\text{m}$	200 - 320 $\mu\text{m}$	400 $\mu\text{m}$	unknown
Power density	Up to 28294W/cm <sup>2</sup>	Up to 28294W/cm <sup>2</sup>	Up to 15915W/cm <sup>2</sup>	Up to 44563W/cm <sup>2</sup>	Up to 3138W/cm <sup>2</sup>	unknown
Aiming beam	diode max 1mW 625 - 670 nm	diode max 1mW 625 - 670 nm	diode max 5mW 640 - 650nm	diode, max 1mW 635 - 650nm	diode max 5mW 640 - 660nm	diode 650nm
Control panel	Touch screen	Touch screen	Touch screen	Touch screen	Touch screen	Touch screen
Activation	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch
Delivery system	Fiber optic cable, handpiece and disposable tips	Fiber optic cable, handpiece and disposable tips	Quartz glass fiber	Fiber optic cable, handpiece and disposable tips	Quartz glass fiber and tips, handpiece and disposable tips	Optical fibers, handpieces and disposable tips
Fiber Tips	Quartz single-use tips varying in length and core diameter (200 – 400 $\mu\text{m}$ )	Quartz single-use tips varying in length and core diameter (200 – 400 $\mu\text{m}$ )	Fiber (400 $\mu\text{m}$ )	Single use tips varying in core diameter (200 - 320 $\mu\text{m}$ )	Quartz tips (400 $\mu\text{m}$ )	Single use tips
Materials	Medical grade plastics, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components	Medical grade plastics, stainless steel, and electronic parts and components

# BIOLASE

## Intended use and Indications for Use

Epic 980 (subject device)	Epic 980 K192430	QuickLase 810,980 & Dual+ K100474	SiroLaser Advance K103753	Elumi 810 + 980 K152032	Curative 980 K082445
Dental soft tissue indications: incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:	Dental soft tissue indications: Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:	Intended for incision, excision, vaporization, hemostasis and treatment of oral soft-tissue. Examples:	Indicated for intra and extraoral surgery including incision, excision, hemostasis, coagulation and vaporization of soft-tissues including marginal and interdental gingival and epithelial lining of free gingiva and is indicated for:	Soft tissue laser intended for the incision, excision, vaporization, hemostasis and treatment of oral soft-tissues. the following are the oropharyngeal indications for use:	Indicated for incision, excision, vaporization, ablation and coagulation of oral soft-tissues (intraoral and extraoral) including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:
excisional and incisional biopsies	excisional and incisional biopsies	excisional and incisional biopsies	biopsies	excisional and incisional biopsies	excisional and incisional biopsies
exposure of unerupted teeth	exposure of unerupted teeth	exposure of unerupted teeth	exposure of unerupted/partially erupted teeth	exposure of unerupted teeth	exposure of unerupted/partially erupted teeth
fibroma removal	fibroma removal	fibroma removal	fibroma removal	fibroma removal	fibroma removal
frenectomy	frenectomy	frenectomy	frenectomy	frenectomy	frenectomy
frenotomy	frenotomy	frenotomy	frenotomy	frenotomy	frenotomy
gingival troughing for crown impressions	gingival troughing for crown impressions	gingival troughing for crown impressions	gingival troughing	gingival troughing for crown impressions	gingival troughing for crown impressions
gingivectomy	gingivectomy	gingivectomy	gingivectomy	gingivectomy	gingivectomy
gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty	gingivoplasty

# BIOLASE

gingival incision and excision	gingival incision and excision	gingival incision and excision	gingival incision and excision	gingival incision and excision	gingival incision and excision
hemostasis and coagulation	hemostasis and coagulation	hemostasis and coagulation	hemostasis of donor site	hemostasis and coagulation	hemostasis and coagulation
implant recovery	implant recovery	implant recovery	implant recovery	implant recovery	implant recovery
incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess	incision and drainage of abscess
leukoplakia	leukoplakia	leukoplakia	leukoplakia	leukoplakia	leukoplakia
operculectomy	operculectomy	operculectomy	operculectomy	operculectomy	operculectomy
oral papillectomies	oral papillectomies	oral papillectomies	papillectomy	oral papillectomies	oral papillectomies
pulpotomy	pulpotomy	pulpotomy	pulpotomy	pulpotomy	pulpotomy
pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy	pulpotomy as an adjunct to root canal therapy
reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy	reduction of gingival hypertrophy
soft-tissue crown lengthening	soft-tissue crown lengthening	soft-tissue crown lengthening	crown lengthening	soft-tissue crown lengthening	soft-tissue crown lengthening
treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa	treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty	vestibuloplasty
tissue retraction for impression	tissue retraction for impression	tissue retraction for impression	tissue retraction for impression	tissue retraction for impression	tissue retraction for impression
laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage	laser soft-tissue curettage



# BIOLASE

circulation; the temporary relaxation of muscle.	circulation; the temporary relaxation of muscle.	circulation; the temporary relaxation of muscle.	circulation; the temporary relaxation of muscle.	circulation; the temporary relaxation of muscle.
Reduction of bacterial level(decontamination) and inflammation	NA	Reduction of bacterial level (decontamination) and inflammation	NA	Reduction of bacterial level (decontamination) and inflammation
Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium	NA	Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium	NA	Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
Lesion (tumor) removal	NA	Lesion (tumor) removal	NA	Lesion (tumor) removal
Laser assisted flap surgery	NA	NA	Laser assisted flap surgery	Laser assisted flap surgery
Removal of granulation tissue	NA	NA	Removal of granulation tissue	Removal of granulation tissue
Removal of hyperplastic tissues	NA	NA	Removal of hyperplastic tissues	NA

## VII. PERFORMANCE DATA

### Clinical and Bench Testing

Since the expanded indications for use have been already cleared for equivalent devices, therefore any additional clinical and/or performance testing was not required.

### Biocompatibility and Sterilization Testing

No new biocompatibility and sterilization testing were performed. All patient-contacting accessories remain the same as previously cleared under K192430.

### Electrical Safety and Electromagnetic Compatibility (EMC)

All relevant electrical safety and EMC testing have been conducted in accordance with current recognized standards. The Epic 980 diode laser complies with the requirements.

IEC 60601-1-2:2014

Medical electrical equipment- Part 1-2- electromagnetic compatibility (EMC)

IEC 60601-1:2012

Medical electrical equipment – Part 1: general requirements for basic safety and essential performance

IEC 60601-2-22:2007+ A1:2012

Medical electrical equipment- Part 2-22: particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60825-1:2014

Safety of laser products- Part 1: equipment classification and requirements

IEC 80601-2-60:2012

Medical electrical equipment – Part 2-60: particular requirements for the basic safety and essential performance of dental equipment

### Software Verification and Validation

Software contained in Epic 980 was developed, tested and documented in accordance with IEC 62304:2015 – Medical Device Software - Software Lifecycle and the FDA guidance document “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices”. Verification and validation testing demonstrate performance according to specifications and functions intended.

## VIII. CONCLUSION

Comparison of the Epic 980 subject device with the predicate devices demonstrate substantial equivalence in technological and performance characteristics and supports the safety and effectiveness of the Epic 980 for the stated indications for use.



Florida Board of Dentistry  
Department of Health, Board of Dentistry  
4052 Bald Cypress Way Bin C-04  
Tallahassee, FL 32399-3258  
Phone 850-245-4463  
Attn: Jessica Sapp, Executive Director  
Email: [Jessica.Sapp@flhealth.gov](mailto:Jessica.Sapp@flhealth.gov)

July 1, 2021

Dear Jessica,  
Attached please find *A Pilot Study to Determine the Effectiveness of Laser Bacterial Reduction in the Management of Periodontal Diseases, Proposal and inquiry from Academy of Laser Dentistry* to be considered by the Florida Hygiene Council at their July 13, 2021 meeting.

Please let me know that you receive this successfully.

Sincerely,

A handwritten signature in black ink that reads "Gail S. Siminovsky". The signature is written in a cursive style with a light blue highlight behind it.

Gail Siminovsky, CAE  
Executive Director

## A Study to Determine the Effectiveness of Laser Bacterial Reduction in the Management of Periodontal Diseases

### Proposal and inquiry from Academy of Laser Dentistry

**Question:** Is there an advantage to using a dental laser combined with scaling and root planing to reduce established periodontal pathogens related to periodontal disease? While the effect of periodontal therapy and bacterial reduction is well established, there is very minimal quality evidence that adding sulcular treatment with a diode laser in a “non-surgical” mode is advantageous.

**Hypothesis:** A diode laser in non-cutting mode when placed in the sulcus of a periodontal pocket will decrease the viable count of periodontal pathogens

**Experimental design:** Two groups will be established, one treated with traditional SRP (ultrasonics + hand scaling), the other adding intra-sulcular diode laser treatment with laser bacterial reduction settings. A minimum of 10 patients should be tested, with 3 pockets per patient, ranging from 5-7mm. A paper point should be inserted into the periodontal pockets of each group and sent for PCR testing to establish a baseline level of micro bacteria. The same pockets will be treated then re-tested to determine if there is a reduction in the quantity and quality of the bacteria. The information gathered will be evaluated to determine if bacterial reduction occurs immediately following the procedures.

**Analysis:** The data gathered should be reviewed to establish that there is indeed a reduction in the level of micro-biota following the use of a non-surgical diode laser in the periodontal pocket combined with SRP vs traditional therapy. A satisfactory result will be based on statistical significance.

To demonstrate efficacy, the cohort with SRP and LBR will have a statically significant decrease in periodontal pathogens as opposed to SRP as a mono therapy.

Questions to determine satisfactory evidence for laser bacterial reduction at the request of the Florida Board of Dentistry in addition to FDA Clearance documents to support bacterial reduction and Inflammation

- 1) Can the study utilize PCR paper points or saliva based as Oral DNA to determine decrease in microbiota?
- 2) What is the time period required for evaluation: immediate, 48 hours, 7 days?
- 3) Since the question is bacterial reduction, is it necessary to include clinical parameters as bleeding on probing and Gingival Index and if so at what time points.

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Ron DeSantis**  
Governor

**Scott A. Rivkees, MD**  
State Surgeon General

**Vision:** To be the **Healthiest State** in the Nation

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July 9, 2021

Dr Michael Abdelmalik  
4951 Seaboard Court  
Jacksonville, FL 32210 United States

Dear Dr. Abdelmalik:

Thank you for your application as a Dental. Your application has been received and is pending the following documentation:

*Missing Required Documents*

*A passing score on the ADLEX clinical exam all parts completed within 18 months.*

All parts of the ADEX shall be completed within eighteen (18) months from the initial start of any portion of the examination. A failure to complete all parts of the examination within eighteen (18) months will require the applicant to retake the entire examination.

You can check the status your application at: <https://mgaonline.doh.state.fl.us/>. If you are a returning user, select "Yes" and enter the user ID and password you selected during the registration process under Returning User. If you did not apply for licensure through this screen, select "No" and follow the prompts to create an account. You must have a valid email address to create your account.

To verify we received the documentation, you may want to send your documentation via certified mail, overnight mail, or contact the originating source of outstanding documentation. Additional documentation will be processed in the order it is received.

It is the applicant's responsibility to keep the board office informed of any updates such as address changes, name changes, etc. throughout the application process. Your address can be updated at [www.FLHealthsource.gov/mga-services](http://www.FLHealthsource.gov/mga-services). Once a license is issued, it is automatically mailed to the address and name on record. Such changes after that time may require a duplication fee. Per Section 456.013(1)(a), your current application will expire on 7/3/22. If we do not receive the above item(s) before your application is closed, you will be required to complete another application and application fee.

Thank you for your interest in practicing in Florida. If you have any questions, please contact me at the address below. You may also reach me at (850) 558-9607 or e-mail [john.milton@flhealth.gov](mailto:john.milton@flhealth.gov).

Sincerely,

John Milton  
Regulatory Specialist II

Profession: 701      File No.: 26861

**Council on Dental Hygiene Recommended Rule Amendment**  
**Add American Academy of Dental Hygiene as approved CE provider**  
**Approved by CDH 12/19; initially approved by BOD 02/20; inadvertently omitted from**  
**May, 2020 amendments.**

**64B5-12.013 Continuing Education Requirements; Specific Continuing Education Course Requirements; and Cardiopulmonary Resuscitation (CPR) Certification.**

(1) – (5) No Change

(6) Award of Continuing Education Credit: Continuing education credit shall be awarded only for educational experiences that are specifically appropriate for, and contain useful information directly pertinent to, dentistry or dental hygiene and only if received through the following methods:

(a) No Change.

(b) By taking courses offered by:

1. – 7. No Change.

8. The American Academy of Dental Hygiene.

(c) – (i) No Change

*Rulemaking Authority 456.013(9), 456.0301, 456.031, 466.004(4), 466.0135, 466.014 FS. Law Implemented 456.013(9), 456.0301, 456.031, 456.033, 466.0135, 466.014, 466.017(4) FS. History—New 4-2-86, Amended 12-31-86, 4-26-87, 7-20-87, 9-16-87, 11-18-89, 7-9-90, Formerly 21G-12.013, Amended 5-19-94, 7-18-94, Formerly 61F5-12.013, Amended 11-15-95, 4-8-96, Formerly 59Q-12.013, Amended 2-17-98, 2-15-99, 3-11-99, 11-9-00, 5-20-01, 8-25-03, 5-31-04, 7-13-05, 2-14-06, 12-25-06, 10-10-10, 4-19-18, 8-6-18, 12-11-19.*

OUTLINE OF CHANGES TO DISCIPLINARY GUIDELINES  
CHAPTERS 2021-190 AND 2021-199, LAWS OF FLORIDA  
AUGUST 2021

Chapters 2021-190 and 2021-199, effective July 1, 2021, create two new disciplinary violations in Section 456.072(1), to wit:

**2021-190, LOF (CS for SB 1934)**

Section 1. Paragraph (rr) is added to subsection (1) of section 456.072, Florida Statutes, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(rr) Being convicted or found guilty of, entering a plea of guilty or nolo contendere to, regardless of adjudication, or committing or attempting, soliciting, or conspiring to commit an act that would constitute a violation of any of the offenses listed in s. 456.074(5) or a similar offense in another jurisdiction.

**2021-199, LOF (HB 241)**

Section 9. Paragraph (rr) is added to subsection (1) of section 456.072, Florida Statutes, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(ss) Failure to comply with the parental consent requirements of s. 1014.06.

Accordingly, the Board's Disciplinary Guidelines must be amended to include a penalty range for licensees found guilty of violating one of these new statutory sections. Were the Board to agree, two new paragraphs would be added to the end of Rule 64B5-13.005, F.A.C.

VIOLATION	PENALTY RANGE			
	MINIMUM	MAXIMUM	TELEHEALTH REGISTRANT MINIMUM	TELEHEALTH REGISTRANT MAXIMUM
<u>(kkk) Failure to comply with the parental consent requirements of s. 1014.06. (Section 456.072(1)(rr), F.S.)</u>				
<u>First Offense</u>	<u>Letter of Concern.</u>	<u>Reprimand and \$500 fine.</u>	<u>Reprimand.</u>	<u>One (1) month suspension.</u>
<u>Second Offense</u>	<u>Reprimand and \$250 fine.</u>	<u>Probation with conditions.</u>	<u>One (1) month suspension.</u>	<u>Six (6) month suspension.</u>
<u>Third or Subsequent Offense</u>	<u>Probation with conditions and \$2,500 fine.</u>	<u>One (1) year suspension and \$5,000 fine.</u>	<u>One (1) year suspension.</u>	<u>Denial or revocation of License.</u>
<u>(lll) Convicted / guilty of crime enumerated in 456.074(5), F.S. or a similar offense. (Section 456.072(1)(ss), F.S.)</u>				
<u>First Offense</u>	<u>Denial or revocation of license.</u>	<u>Denial or revocation of license and \$5,000 fine.</u>	<u>Denial or revocation of license.</u>	<u>Same.</u>
<u>Second or Subsequent Offense</u>	<u>Denial or revocation of license and \$2,500 fine.</u>	<u>Denial/revocation of license and \$10,000 fine.</u>	<u>Denial or revocation of license.</u>	<u>Same.</u>

## CHAPTER 2021-190

### Committee Substitute for Senate Bill No. 1934

An act relating to health care practitioner discipline; amending s. 456.072, F.S.; subjecting health care practitioners to disciplinary action for specified offenses; amending s. 456.074, F.S.; revising provisions relating to immediate suspension of licensure to apply to all health care practitioners; requiring the Department of Health to issue emergency orders to suspend health care practitioners' licenses if they enter a criminal plea to, or are convicted or found guilty of, a felony relating to homicide or are arrested for committing or attempting, soliciting, or conspiring to commit acts that would constitute violations of specified criminal offenses; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (rr) is added to subsection (1) of section 456.072, Florida Statutes, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(rr) Being convicted or found guilty of, entering a plea of guilty or nolo contendere to, regardless of adjudication, or committing or attempting, soliciting, or conspiring to commit an act that would constitute a violation of any of the offenses listed in s. 456.074(5) or a similar offense in another jurisdiction.

Section 2. Present subsection (5) of section 456.074, Florida Statutes, is redesignated as subsection (6), a new subsection (5) is added to that section, and subsection (1) of that section is amended, to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(1) The department shall issue an emergency order suspending the license of any health care practitioner ~~person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484~~ who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication, any of the following to:

(a) A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or under 42 U.S.C. ss. 1395-1396.;

(b) A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program; ~~or~~

(c) A felony under s. 784.086, relating to a reproductive battery.

(d) A felony under chapter 782, relating to homicide.

(5) The department shall issue an emergency order suspending the license of any health care practitioner who is arrested for committing or attempting, soliciting, or conspiring to commit any act that would constitute a violation of any of the following criminal offenses in this state or similar offenses in another jurisdiction:

(a) Section 393.135(2), relating to sexual misconduct with an individual with a developmental disability.

(b) Section 394.4593(2), relating to sexual misconduct with a patient who resides in a receiving or treatment facility or is otherwise in the custody of the Department of Children and Families.

(c) Section 787.01, relating to kidnapping.

(d) Section 787.02, relating to false imprisonment.

(e) Section 787.025(2), relating to luring or enticing a child.

(f) Section 787.06(3)(b), (d), (f), or (g), relating to human trafficking for commercial sexual activity.

(g) Former s. 787.06(3)(h), relating to human trafficking of a child under the age of 15 for commercial sexual activity.

(h) Section 787.07, relating to human smuggling.

(i) Section 794.011, relating to sexual battery, excluding s. 794.011(10).

(j) Section 794.05, relating to unlawful sexual activity with certain minors.

(k) Section 794.08, relating to female genital mutilation.

(l) Former s. 796.03, relating to procuring a person under the age of 18 for prostitution.

(m) Former s. 796.035, relating to the selling or buying of minors into prostitution.

(n) Section 796.04, relating to forcing, compelling, or coercing another to become a prostitute.

(o) Section 796.05, relating to deriving support from the proceeds of prostitution.

(p) Section 796.07(4)(a)3., relating to a felony of the third degree for a third or subsequent violation of s. 796.07, relating to prohibiting prostitution and related acts.

(q) Section 800.04, relating to lewd or lascivious offenses committed upon or in the presence of persons younger than 16 years of age.

(r) Section 810.145(8), relating to video voyeurism of a minor.

(s) Section 825.1025, relating to lewd or lascivious offenses committed upon or in the presence of an elderly person or disabled person.

(t) Section 827.071, relating to sexual performance by a child.

(u) Section 847.011, relating to prohibited acts in connection with obscene, lewd, and other materials.

(v) Section 847.012, relating to materials harmful to minors.

(w) Section 847.013, relating to exposing minors to harmful motion pictures, exhibitions, shows, presentations, or representations.

(x) Section 847.0133, relating to the protection of minors from obscene materials.

(y) Section 847.0135, relating to computer pornography, prohibited computer usage, or traveling to meet minors, excluding s. 847.0135(6).

(z) Section 847.0137, relating to the transmission of child pornography by electronic device or equipment.

(aa) Section 847.0138, relating to the transmission of material harmful to minors to a minor by electronic device or equipment.

(bb) Section 847.0145, relating to the selling or buying of minors.

(cc) Section 856.022, relating to loitering or prowling in close proximity to children.

(dd) Section 895.03, relating to racketeering activity, if the court makes a written finding that the racketeering activity involved at least one sexual offense listed in this subsection or at least one offense listed in this subsection which was committed with sexual intent or motive.

(ee) Section 916.1075(2), relating to sexual misconduct against a forensic client of a civil or forensic facility for defendants who have a mental illness or an intellectual disability.

(ff) Section 985.701(1), relating to sexual misconduct against a juvenile offender.

(gg) Any similar offense committed in this state which has been redesignated from a former statute number to one of those listed in this subsection.

Section 3. This act shall take effect July 1, 2021.

Approved by the Governor June 29, 2021.

Filed in Office Secretary of State June 29, 2021.

## CHAPTER 2021-199

### House Bill No. 241

An act relating to Parents' Bill of Rights; creating chapter 1014, F.S.; creating s. 1014.01, F.S.; providing a short title; creating s. 1014.02, F.S.; providing legislative findings; defining the term "parent"; creating s. 1014.03, F.S.; providing that the state, its political subdivisions, other governmental entities, or other institutions may not infringe on parental rights without demonstrating specified information; creating s. 1014.04, F.S.; providing that a parent of a minor child has specified rights relating to his or her minor child; prohibiting the state from infringing upon specified parental rights; providing that certain actions by specified individuals are grounds for disciplinary actions against such individuals; prohibiting specified parental rights from being denied or abridged; providing construction; creating s. 1014.05, F.S.; requiring each district school board to develop and adopt a policy to promote parental involvement in the public school system; providing requirements for such policy; defining the term "instructional materials"; authorizing a district school board to provide such policy electronically or on its website; authorizing a parent to request certain information in writing; providing a procedure for the denial of such information; creating s. 1014.06, F.S.; prohibiting certain health care practitioners and their employees from taking specified actions without a parent's written permission; prohibiting a health care facility from allowing certain actions without a parent's written permission; providing exceptions; providing for disciplinary actions and criminal penalties; amending s. 408.813, F.S.; providing that certain violations relating to parental consent are grounds for administrative fines for health care facilities; amending s. 456.072, F.S.; providing that failure to comply with certain parental consent requirements is grounds for disciplinary action for health care practitioners; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Chapter 1014, Florida Statutes, consisting of ss. 1014.01-1014.06, is created and shall be entitled "Parents' Bill of Rights."

Section 2. Section 1014.01, Florida Statutes, is created to read:

1014.01 Short title.—This section and ss. 1014.02-1014.06 may be cited as the "Parents' Bill of Rights."

Section 3. Section 1014.02, Florida Statutes, is created to read:

1014.02 Legislative findings and definition.—

(1) The Legislature finds that it is a fundamental right of parents to direct the upbringing, education, and care of their minor children. The

Legislature further finds that important information relating to a minor child should not be withheld, either inadvertently or purposefully, from his or her parent, including information relating to the minor child's health, well-being, and education, while the minor child is in the custody of the school district. The Legislature further finds it is necessary to establish a consistent mechanism for parents to be notified of information relating to the health and well-being of their minor children.

(2) For purposes of this chapter, the term "parent" means a person who has legal custody of a minor child as a natural or adoptive parent or a legal guardian.

Section 4. Section 1014.03, Florida Statutes, is created to read:

1014.03 Infringement of parental rights.—The state, any of its political subdivisions, any other governmental entity, or any other institution may not infringe on the fundamental rights of a parent to direct the upbringing, education, health care, and mental health of his or her minor child without demonstrating that such action is reasonable and necessary to achieve a compelling state interest and that such action is narrowly tailored and is not otherwise served by a less restrictive means.

Section 5. Section 1014.04, Florida Statutes, is created to read:

1014.04 Parental rights.—

(1) All parental rights are reserved to the parent of a minor child in this state without obstruction or interference from the state, any of its political subdivisions, any other governmental entity, or any other institution, including, but not limited to, all of the following rights of a parent of a minor child in this state:

(a) The right to direct the education and care of his or her minor child.

(b) The right to direct the upbringing and the moral or religious training of his or her minor child.

(c) The right, pursuant to s. 1002.20(2)(b) and (6), to apply to enroll his or her minor child in a public school or, as an alternative to public education, a private school, including a religious school, a home education program, or other available options, as authorized by law.

(d) The right, pursuant to s. 1002.20(13), to access and review all school records relating to his or her minor child.

(e) The right to make health care decisions for his or her minor child, unless otherwise prohibited by law.

(f) The right to access and review all medical records of his or her minor child, unless prohibited by law or if the parent is the subject of an

investigation of a crime committed against the minor child and a law enforcement agency or official requests that the information not be released.

(g) The right to consent in writing before a biometric scan of his or her minor child is made, shared, or stored.

(h) The right to consent in writing before any record of his or her minor child's blood or deoxyribonucleic acid (DNA) is created, stored, or shared, except as required by general law or authorized pursuant to a court order.

(i) The right to consent in writing before the state or any of its political subdivisions makes a video or voice recording of his or her minor child unless such recording is made during or as part of a court proceeding or is made as part of a forensic interview in a criminal or Department of Children and Families investigation or is to be used solely for the following purposes:

1. A safety demonstration, including the maintenance of order and discipline in the common areas of a school or on student transportation vehicles;

2. A purpose related to a legitimate academic or extracurricular activity;

3. A purpose related to regular classroom instructions;

4. Security or surveillance of buildings or grounds; or

5. A photo identification card.

(j) The right to be notified promptly if an employee of the state, any of its political subdivisions, any other governmental entity, or any other institution suspects that a criminal offense has been committed against his or her minor child, unless the incident has first been reported to law enforcement or the Department of Children and Families and notifying the parent would impede the investigation.

(2) This section does not:

(a) Authorize a parent of a minor child in this state to engage in conduct that is unlawful or to abuse or neglect his or her minor child in violation of general law;

(b) Condone, authorize, approve, or apply to a parental action or decision that would end life;

(c) Prohibit a court of competent jurisdiction, law enforcement officer, or employees of a government agency that is responsible for child welfare from acting in his or her official capacity within the reasonable and prudent scope of his or her authority; or

(d) Prohibit a court of competent jurisdiction from issuing an order that is otherwise permitted by law.

(3) An employee of the state, any of its political subdivisions, or any other governmental entity who encourages or coerces, or attempts to encourage or coerce, a minor child to withhold information from his or her parent may be subject to disciplinary action.

(4) A parent of a minor child in this state has inalienable rights that are more comprehensive than those listed in this section, unless such rights have been legally waived or terminated. This chapter does not prescribe all rights to a parent of a minor child in this state. Unless required by law, the rights of a parent of a minor child in this state may not be limited or denied. This chapter may not be construed to apply to a parental action or decision that would end life.

Section 6. Section 1014.05, Florida Statutes, is created to read:

1014.05 School district notifications on parental rights.—

(1) Each district school board shall, in consultation with parents, teachers, and administrators, develop and adopt a policy to promote parental involvement in the public school system. Such policy must include:

(a) A plan, pursuant to s. 1002.23, for parental participation in schools to improve parent and teacher cooperation in such areas as homework, school attendance, and discipline.

(b) A procedure, pursuant to s. 1002.20(19)(b), for a parent to learn about his or her minor child's course of study, including the source of any supplemental education materials.

(c) Procedures, pursuant to s. 1006.28(2)(a)2., for a parent to object to instructional materials and other materials used in the classroom. Such objections may be based on beliefs regarding morality, sex, and religion or the belief that such materials are harmful. For purposes of this section, the term "instructional materials" has the same meaning as in s. 1006.29(2) and may include other materials used in the classroom, including workbooks and worksheets, handouts, software, applications, and any digital media made available to students.

(d) Procedures, pursuant to s. 1002.20(3)(d), for a parent to withdraw his or her minor child from any portion of the school district's comprehensive health education required under s. 1003.42(2)(n) that relates to sex education or instruction in acquired immune deficiency syndrome education or any instruction regarding sexuality if the parent provides a written objection to his or her minor child's participation. Such procedures must provide for a parent to be notified in advance of such course content so that he or she may withdraw his or her minor child from those portions of the course.

(e) Procedures, pursuant to s. 1006.195(1)(a), for a parent to learn about the nature and purpose of clubs and activities offered at his or her minor

child's school, including those that are extracurricular or part of the school curriculum.

(f) Procedures for a parent to learn about parental rights and responsibilities under general law, including all of the following:

1. Pursuant to s. 1002.20(3)(d), the right to opt his or her minor child out of any portion of the school district's comprehensive health education required under s. 1003.42(2)(n) that relates to sex education instruction in acquired immune deficiency syndrome education or any instruction regarding sexuality.

2. A plan to disseminate information, pursuant to s. 1002.20(6), about school choice options, including open enrollment.

3. In accordance with s. 1002.20(3)(b), the right of a parent to exempt his or her minor child from immunizations.

4. In accordance with s. 1008.22, the right of a parent to review statewide, standardized assessment results.

5. In accordance with s. 1003.57, the right of a parent to enroll his or her minor child in gifted or special education programs.

6. In accordance with s. 1006.28(2)(a)1., the right of a parent to inspect school district instructional materials.

7. In accordance with s. 1008.25, the right of a parent to access information relating to the school district's policies for promotion or retention, including high school graduation requirements.

8. In accordance with s. 1002.20(14), the right of a parent to receive a school report card and be informed of his or her minor child's attendance requirements.

9. In accordance with s. 1002.23, the right of a parent to access information relating to the state public education system, state standards, report card requirements, attendance requirements, and instructional materials requirements.

10. In accordance with s. 1002.23(4), the right of a parent to participate in parent-teacher associations and organizations that are sanctioned by a district school board or the Department of Education.

11. In accordance with s. 1002.222(1)(a), the right of a parent to opt out of any district-level data collection relating to his or her minor child not required by law.

(2) A district school board may provide the information required in this section electronically or post such information on its website.

(3) A parent may request, in writing, from the district school superintendent the information required under this section. Within 10 days, the district school superintendent must provide such information to the parent. If the district school superintendent denies a parent's request for information or does not respond to the parent's request within 10 days, the parent may appeal the denial to the district school board. The district school board must place a parent's appeal on the agenda for its next public meeting. If it is too late for a parent's appeal to appear on the next agenda, the appeal must be included on the agenda for the subsequent meeting.

Section 7. Section 1014.06, Florida Statutes, is created to read:

1014.06 Parental consent for health care services.—

(1) Except as otherwise provided by law, a health care practitioner, as defined in s. 456.001, or an individual employed by such health care practitioner may not provide or solicit or arrange to provide health care services or prescribe medicinal drugs to a minor child without first obtaining written parental consent.

(2) Except as otherwise provided by law or a court order, a provider, as defined in s. 408.803, may not allow a medical procedure to be performed on a minor child in its facility without first obtaining written parental consent.

(3) This section does not apply to an abortion, which is governed by chapter 390.

(4) This section does not apply to services provided by a clinical laboratory, unless the services are delivered through a direct encounter with the minor at the clinical laboratory facility. For purposes of this subsection, the term "clinical laboratory" has the same meaning as provided in s. 483.803.

(5) A health care practitioner or other person who violates this section is subject to disciplinary action pursuant to s. 408.813 or s. 456.072, as applicable, and commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 8. Paragraph (f) is added to subsection (3) of section 408.813, Florida Statutes, to read:

408.813 Administrative fines; violations.—As a penalty for any violation of this part, authorizing statutes, or applicable rules, the agency may impose an administrative fine.

(3) The agency may impose an administrative fine for a violation that is not designated as a class I, class II, class III, or class IV violation. Unless otherwise specified by law, the amount of the fine may not exceed \$500 for each violation. Unclassified violations include:

(f) Violating the parental consent requirements of s. 1014.06.

Section 9. Paragraph (rr) is added to subsection (1) of section 456.072, Florida Statutes, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(rr) Failure to comply with the parental consent requirements of s. 1014.06.

Section 10. This act shall take effect July 1, 2021.

Approved by the Governor June 29, 2021.

Filed in Office Secretary of State June 29, 2021.

**BOARD COUNSEL INITIAL DRAFT LANGUAGE  
DISCIPLINARY PENALY RANGES FOR TELEHEALTH REGISTRANTS  
AUGUST, 2021.**

**Statutory Authority:**

456.47 Use of telehealth to provide services.—

(i) The board, or the department if there is no board, may take disciplinary action against an out-of-state telehealth provider registered under this subsection if the registrant:

1. Fails to notify the applicable board, or the department if there is no board, of any adverse actions taken against his or her license as required under paragraph (d).
2. Has restrictions placed on or disciplinary action taken against his or her license in any state or jurisdiction.
3. Violates any of the requirements of this section.
4. Commits any act that constitutes grounds for disciplinary action under s. 456.072(1) or the applicable practice act for Florida-licensed providers.

Disciplinary action taken by a board, or the department if there is no board, under this paragraph may include suspension or revocation of the provider’s registration or the issuance of a reprimand or letter of concern. A suspension may be accompanied by a corrective action plan as determined by the board, or the department if there is no board, the completion of which may lead to the suspended registration being reinstated according to rules adopted by the board, or the department if there is no board.

**64B5-13.005 Disciplinary Guidelines.**

(1) When the Board finds an applicant, licensee, ~~or~~ certificate holder, or telehealth registrant whom it regulates under chapter 466, F.S., has committed any of the acts set forth in section 456.072(1), ~~or~~ 466.028, or 456.47, F.S., it shall issue a final order imposing appropriate penalties as recommended in these disciplinary guidelines. For any violation found that is for fraud or making a false or fraudulent representation, the Board will impose a fine of \$10,000.00 per count or offense. The use of terms to describe the offenses herein within the individual guidelines is intended to be only a generally descriptive use of the terms. For an accurate description of the actual offenses, the reader should refer to the statutory disciplinary provisions. The maximum penalties set forth in any individual offense guideline include all of the less severe penalties that would fall in between the maximum and the minimum penalties stated. For telehealth registrants, a suspension may be accompanied by a corrective action plan that addresses the conduct which resulted in the underlying disciplinary violations. The Board may require a corrective action plan be completed prior to reinstatement of the suspended registration or the corrective action plan may follow a suspension for a definite term.

VIOLATION	PENALTY RANGE		TELEHEALTH REGISTRANT MINIMUM	TELEHEALTH REGISTRANT MAXIMUM
	MINIMUM	MAXIMUM		
(a) Attempting to obtain, obtaining or renewing a license by bribery, fraudulent misrepresentations or error of the Board. (Sections 466.028(1)(a), 456.072(1)(h), F.S.)				
First Offense	Denial \$500 fine and referral	Denial/revocation \$10,000 fine and	<b>Denial of Application.</b>	<b>Revocation or Denial of Application.</b>

	to State Attorney's office if not licensed.	referral to State Attorney's office if not licensed.		
Second Offense	Probation with conditions \$500 fine.	Revocation \$10,000 fine permanent denial and revocation.	Revocation or Denial	Same.
(b) Having a license to practice dentistry or dental hygiene revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another state, territory, or country. (Sections 466.028(1)(b), 456.072(1)(f), F.S.)				
First Offense	\$1,000 fine.	Suspension/denial until the license is unencumbered and active in the jurisdiction in which the disciplinary action was originally taken, or up to five years followed by probation and \$10,000 fine or revocation.	Letter of Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Imposition of discipline which would have been imposed if the substantive violation occurred in Florida. Probation and \$1,000 fine.	Suspension until the license is unencumbered in the jurisdiction in which disciplinary action was taken and \$10,000 fine.	One (1) month suspension.	Three (3) year Suspension.
Third Offense	One year suspension followed by probation and \$5,000 fine.	Revocation and permanent denial and \$10,000 fine.	One (1) year suspension.	Revocation.
(c) Guilty of a crime directly relating to practice or ability to practice.				

(Sections 466.028(1)(c), 456.072(1)(c), F.S.)				
First Offense	\$1,000 fine.	Denial or 2 years suspension, 2 years probation with conditions and \$10,000 fine, or revocation.	One (1) month Suspension	Three (3) year Suspension or Denial of Application.
Second Offense	One year suspension followed by probation and \$1,000 fine.	Denial or revocation and \$10,000 fine, with conditions.	Six (6) month Suspension.	Revocation
Third Offense	Revocation and \$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension	Revocation
(d) Advertising goods or services in a manner which is fraudulent, false, deceptive, or misleading in form. (Section 466.028(1)(d), F.S.)				
First Offense	\$500 fine.	1 year probation with conditions and \$10,000 fine.	One (1) month Suspension	One (1) year Suspension or Denial of Application..
Second Offense	1 year probation with conditions and \$3,000 fine.	1 year suspension 2 years probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Eighteen (18) month Suspension.
Third Offense	2 years probation with conditions and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension	Revocation
(e) Advertising, practicing, or attempting to practice under a name other than one's own. (Section 466.028(1)(e), F.S.)				
First Offense	\$1,000 fine.	1 year suspension and \$10,000 fine.	Reprimand	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$3,000 fine.	Denial or revocation and \$10,000 fine.	Six (6) month Suspension	Revocation
Third Offense	Probation with conditions and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(f) Failing to report any person in violation of this chapter or of the rules of the department or the board. (Sections 466.028(1)(f),				

456.072(1)(i), F.S.)				
First Offense	\$500 fine.	1 year probation with conditions and \$1,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	1 year probation with conditions and \$1,000 fine.	6 months suspension, 1 year probation with conditions and \$3,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	1 year probation with conditions and \$3,000 fine.	1 year suspension, 1 year probation with conditions and \$5,000 fine.	One (1) year Suspension.	Revocation.
(g) Aiding, assisting, procuring, or advising any unlicensed person to practice dentistry or dental hygiene. (Sections 466.028(1)(g), 456.072(1)(j), F.S.)				
First Offense	\$1,000 fine.	6 months suspension, 1 year probation with conditions and \$10,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	1 year suspension, 2 years probation with conditions and \$5,000 fine.	2 years suspension, 2 years probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	2 years suspension followed by 2 years probation with conditions and \$10,000 fine.	Denial/revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(h) Being employed by any corporation, organization, group, or person other than a dentist or a professional corporation or limited liability company composed of dentists to practice dentistry. (Section 466.028(1)(h), F.S.)				
First Offense	\$1,000 fine.	2 years probation with conditions and up to suspension, and \$10,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	1 year probation	Suspension, 1 year	Six (6) month	Revocation.

	with conditions, reprimand and \$3,000 fine.	probation with conditions and \$10,000 fine.	Suspension.	
Third Offense	1 year suspension, reprimand and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(i) Failing to perform any statutory or legal obligation placed upon a licensee. (Sections 466.028(1)(i), 456.072(1)(k), F.S.)				
First Offense	\$500 fine.	2 years probation with conditions and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	1 year probation with conditions and \$1,000 fine.	2 years probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	2 years probation with conditions and \$2,000 fine.	1 year suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(j) Making or filing a false report, failing to file a report or record required by state or federal law, knowingly impeding or obstructing such filing. (Sections 466.028(1)(j), 456.072(1)(l), F.S.)				
First Offense	\$1,000 fine.	1 year probation with conditions and up to suspension, and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	1 year probation with conditions and \$2,500 fine.	Suspension, probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	2 years probation with conditions and \$5,000 fine.	Denial/revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(k) Sexual battery, as defined in chapter 794, F.S., upon a patient. (Section 466.028(1)(k), F.S.)				
First Offense	6 months suspension followed by	Denial or revocation and \$10,000 fine.	Denial or Revocation.	Same.

	probation and \$2,500 fine.			
Second or Subsequent Offense	5 years suspension followed by probation with conditions and \$5,000 fine.	Denial/revocation and \$10,000 fine.	Denial or Revocation.	Same.
(l) Making deceptive, untrue, or fraudulent representations in or related to the practice of dentistry. (Sections 466.028(1)(l), 456.072(1)(a), F.S.)				
First Offense	\$1,000 fine.	6 months probation with conditions and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	1 year probation with conditions and \$1,000 fine.	6 months suspension and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	2 years probation with conditions and \$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(m) Failing to keep written records and history justifying the course of treatment of the patient. (Section 466.028(1)(m), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$7,500 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$1,000 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Probation with conditions and \$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(n) Failing to make available to a patient or client, copies of documents which relate to the patient or client. (Section 466.028(1)(n), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$7,500 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.

Third Offense	\$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(o) Performing professional services which have not been authorized by the patient or client. (Section 466.028(1)(o), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(p) Prescribing, procuring, dispensing, administering, mixing, or otherwise preparing a legend drug or controlled substance, other than in the course of the professional practice of the dentist. (Section 466.028(1)(p), F.S.)				
First Offense	\$500 fine.	Probation with conditions, \$10,000 fine and up to suspension.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Suspension followed by probation and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(q) Prescribing any medicinal drug scheduled in chapter 893, F.S., to herself or himself. (Section 466.028(1)(q), F.S.)				
First Offense	\$500 fine.	Suspension followed by probation with conditions and \$10,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Suspension followed by	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.

	probation and \$5,000 fine.			
(r) Prescribing any drug which is a Schedule II amphetamine or a Schedule II sympathomimetic amine drug, pursuant to chapter 893, F.S. (Section 466.028(1)(r), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension followed by probation and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Probation with conditions and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(s) Being unable to practice her or his profession with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. (Sections 466.028(1)(s), 456.072(1)(z), F.S.)				
First Offense	Denial, or suspension until licensee petitions the Board and demonstrates ability to practice with reasonable skill and safety, followed by probation with conditions and up to \$5,000 fine.		Denial of Application or Suspension until demonstration of ability to practice with reasonable skill and safety.	Two (2) year suspension, demonstration of ability to practice with reasonable skill and safety as condition of reinstatement.
Second Offense	Denial, or suspension until licensee petitions the Board and	Suspension followed by probation and \$10,000 fine.	Two (2) year suspension, demonstration of ability to practice with reasonable skill	Revocation.

	demonstrates ability to practice with reasonable skill and safety, followed by probation with conditions and up to \$5,000 fine.		and safety as condition of reinstatement.	
Third Offense	Denial, or suspension until licensee petitions the Board and demonstrates ability to practice with reasonable skill and safety, followed by probation with conditions and up to \$10,000 fine.	Revocation and \$10,000 fine.	Five (5) year suspension, demonstration of ability to practice with reasonable skill and safety as condition of reinstatement.	Revocation.
(t) Fraud, deceit, or misconduct in the practice of dentistry or dental hygiene. (Section 466.028(1)(t), F.S.)				
First Offense	\$2,500 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$8,000 fine.	Suspension followed by probation and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$10,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(u) Failure to provide and maintain reasonable sanitary facilities and conditions. (Section 466.028(1)(u), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$8,000 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	Probation with conditions and \$3,000 fine.	Suspension, probation with conditions and	Not Applicable to Telehealth Registrants.	

		\$10,000 fine.		
Third Offense	Probation with conditions and \$8,000 fine.	Revocation and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
(v) Failure to provide adequate radiation safeguards. (Section 466.028(1)(v), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$8,000 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	Probation with conditions and \$3,000 fine.	Suspension followed by probation and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
Third Offense	Probation with conditions and \$8,000 fine.	Revocation and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
(w) Performing any procedure which would constitute experimentation on human subjects, without first obtaining full, informed, and written consent. (Section 466.028(1)(w), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$3,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$3,500 fine.	Suspension followed by probation and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Suspension followed by probation and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(x) Being guilty of incompetence or negligence, including, but not limited to, being guilty of dental malpractice. (Section 466.028(1)(x), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$10,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$1,000 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.

(y) Practicing beyond the scope that she or he is competent to perform. (Sections 466.028(1)(y), 456.072(1)(o), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$10,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$1,000 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(z) Delegating or contracting for professional responsibilities to a person who is not qualified to perform them. (Sections 466.028(1)(z), 456.072(1)(p), F.S.)				
First Offense	\$2,500 fine.	Probation with conditions, \$10,000 fine and suspension.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$5,000 fine.	Suspension followed by probation and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Probation with conditions and \$7,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
Any violation of section 466.028(1)(z), F.S., will result in a minimum licensure suspension of six months, in addition to any other penalty authorized for this violation, except where revocation is imposed.				
(aa) The violation of a lawful order of the board, or failure to comply with subpoena of the board or department. (Sections 466.028(1)(aa), 456.072(1)(q), F.S.)				
First Offense	\$5,000 fine.	Suspension until compliant with order or subpoena, probation with conditions and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$10,000 fine.	Suspension until compliant with order or subpoena followed by	Six (6) month Suspension.	One (1) year Suspension.

		probation with conditions and \$10,000 fine.		
Third Offense	Revocation and \$10,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(bb) Conspiring with another licensee or with any person to commit an act, which would tend to coerce, intimidate, or preclude another licensee from advertising services. (Section 466.028(1)(bb), F.S.)				
First Offense	\$1,000 fine.	\$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(cc) Being adjudged mentally incompetent in this or any other state, the discipline for which shall last only so long as the adjudication. (Section 466.028(1)(cc), F.S.)				
First and any subsequent offense.	Suspension until adjudged competent by same court.	Suspension until adjudged competent by same court.	Denial of Application or suspension until adjudged competent by same court.	Same.
(dd) Presigning blank prescription or laboratory work order forms. (Section 466.028(1)(dd), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$500 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$1,000 fine.	Probation with conditions and \$7,500 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(ee) Prescribing growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of				

muscle building or to enhance athletic performance. (Section 466.028(1)(ee), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$5,000 fine.	Suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(ff) Operating a dental office such as to result in dental treatment that is below minimum acceptable standards of performance for the community. (Section 466.028(1)(ff), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$4,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(gg) Administering anesthesia in a manner which violates rules of the board. (Section 466.028(1)(gg), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
Third Offense	Probation with conditions and \$4,000 fine.	Revocation and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
(hh) Failing to report any licensee under chapter 458 or 459, F.S., who the dentist knows has violated the grounds for disciplinary action. (Section 466.028(1)(hh), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.

Second Offense	\$2,500 fine.	\$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	\$3,500 fine.	\$10,000 fine.	One (1) year Suspension.	Revocation.
(ii) Failing to report to the board, within 30 days action has been taken against one's license to practice dentistry in another state, territory, or country. (Section 466.028(1)(ii), F.S.)				
First Offense	\$1,000 fine.	Denial, revocation and \$8,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation and \$1,500 fine.	Denial, revocation and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Suspension followed by probation and \$3,000 fine.	Denial, revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(jj) Advertising specialty services in violation of this chapter. (Section 466.028(1)(jj), F.S.)				
First Offense	\$1,000 fine.	\$7,500 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$2,500 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Suspension followed by probation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(kk) Allowing any person to interfere with a dentist's clinical judgment. (Section 466.028(1)(kk), F.S.)				
First Offense	\$1,000 fine.	\$5,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(ll) Violating any provision of Chapters 456 and 466, F.S., or				

any rules adopted pursuant thereto. (Sections 466.028(1)(mm), 456.072(1)(b), 456.072(1)(dd), F.S.)				
First Offense	\$750 fine.	Probation with conditions and \$10,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	Probation with conditions and \$1,000 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$2,500 fine.	Suspension followed by probation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(mm) Failing to comply with the educational course requirements for HIV. (Section 456.072(1)(e), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$1,500 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	\$1,000 fine.	Probation with conditions and \$5,000 fine.	Not Applicable to Telehealth Registrants.	
Third Offense	\$1,500 fine.	Probation with conditions and \$7,500 fine.	Not Applicable to Telehealth Registrants.	
(nn) Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the department against another licensee. (Section 456.072(1)(g), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$3,500 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(oo) Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the				

practice of a profession. (Section 456.072(1)(m), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$3,500 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Suspension and \$10,000 fine.	One (1) year Suspension.	Revocation.
(pp) Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party. (Section 456.072(1)(n), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Probation with conditions and \$3,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(qq) Wrong patient, wrong-site procedure, a wrong procedure, medically unnecessary. (Section 456.072(1)(bb), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Reprimand or Denial of Application.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$2,000 fine.	Suspension followed by probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Suspension followed by probation with conditions and \$3,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(rr) Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding. (Section 456.072(1)(r), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and	Reprimand.	Six (6) month Suspension or Denial of

		\$10,000 fine.		Application.
Second Offense	Probation with conditions and \$2,500 fine.	Suspension followed by probation and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	Probation with conditions and \$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(ss) Failing to comply with the educational course requirements for domestic violence. (Section 456.072(1)(s), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$2,500 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	Probation with conditions and \$1,000 fine.	Probation with conditions and \$4,000 fine.	Not Applicable to Telehealth Registrants.	
Third Offense	\$2,500 fine.	Probation with conditions and \$8,000 fine.	Not Applicable to Telehealth Registrants.	
(tt) Failing to comply with sections 381.026 and 381.0261, F.S., patient rights and how to file a patient complaint. (Section 456.072(1)(u), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$2,500 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	Probation with conditions and \$1,000 fine.	Probation with conditions and \$4,000 fine.	Not Applicable to Telehealth Registrants.	
Third Offense	\$2,500 fine.	Probation with conditions and \$8,000 fine.	Not Applicable to Telehealth Registrants.	
(uu) Engaging or attempting to engage in sexual misconduct as defined and prohibited in section 456.063(1), F.S. (Section 456.072(1)(v), F.S.)				
First Offense	\$2,500 fine.	Revocation or probation with conditions and \$10,000 fine.	One (1) year suspension.	Revocation or Denial of Application.
Second Offense	Probation with conditions and \$5,000 fine.	Suspension followed by probation with	Revocation	Same

		conditions or revocation, and \$10,000 fine.		
Third Offense	Suspension followed by probation with conditions and \$8,000 fine.	Revocation and \$10,000 fine.	Revocation	Same
(vv) Failing to report to the board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to regardless of adjudication, a crime in any jurisdiction. (Section 456.072(1)(x), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$10,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$1,000 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	Suspension followed by probation with conditions and \$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(ww) Using information about people involved in motor vehicle accidents which has been derived from accident reports. (Section 456.072(1)(y), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$5,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	\$1,000 fine.	Probation with conditions and \$8,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$2,500 fine.	Suspension followed by probation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(xx) Leaving a foreign body in a patient. (Section 456.072(1)(cc), F.S.)				
First Offense	\$1,000 fine.	Probation with conditions and	Not Applicable to Telehealth Registrants.	

		\$10,000 fine.		
Second Offense	Probation with conditions and \$2,500 fine.	Suspension followed by probation with conditions and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
Third Offense	Probation with conditions and \$5,000 fine.	Suspension and/or revocation and \$10,000 fine.	Not Applicable to Telehealth Registrants.	
(yy) Testing positive for any drug, on any preemployment or employer-ordered drug screening. (Section 456.072(1)(aa), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	Six (6) month Suspension or Denial of Application.
Second Offense	\$1,000 fine.	Suspension followed by probation with conditions and \$10,000 fine.	Six (6) month Suspension.	One (1) year Suspension.
Third Offense	\$2,500 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(zz) Intentionally submitting a personal injury protection claim required by section 627.736, F.S., statement that has been “upcoded” as defined in section 627.732, F.S. (Section 456.072(1)(ee), F.S.)				
First Offense	\$500 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$2,500 fine.	Suspension followed by probation with conditions and \$10,000 fine.	One (1) year Suspension.	Revocation.
(aaa) Intentionally submitting a personal injury protection claim required by section 627.736, F.S., for services that were not rendered. (Section 456.072(1)(ff), F.S.)				
First Offense	\$500 fine.	Probation with	Reprimand.	One (1) year

		conditions and \$8,000 fine.		Suspension or Denial of Application.
Second Offense	\$1,000 fine.	Probation with conditions and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$2,500 fine.	Suspension followed by probation with conditions and \$10,000 fine.	One (1) year Suspension.	Revocation.
(bbb) Engaging in a pattern of practice of prescribing medicinal drugs or controlled substances which demonstrates a lack of reasonable skill or safety to patients or a violation of sections 893.055 and 893.0551, F.S., or law and rules relating to prescribing practitioners. (Section 456.072(1)(gg), F.S.)				
First Offense	\$1,500 fine.	Probation with conditions and \$8,000 fine.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Probation with conditions and \$3,000 fine.	Suspension and \$10,000 fine.	Six (6) month Suspension.	Revocation.
Third Offense	\$5,000 fine.	Revocation and \$10,000 fine.	One (1) year Suspension.	Revocation.
(ccc) Failing to comply with, failing to successfully complete, or being terminated from an impaired practitioner treatment program. (Section 456.072(1)(hh), F.S.)				
First Offense	Suspension, until compliant, followed by 2 years probation with conditions and \$2,000 fine.	Suspension until compliant, followed by 5 years probation with conditions and \$5,000 fine.	Denial of Application or Suspension until Complaint, followed by Corrective Action Plan.	Same
Second or Subsequent Offense	Three years suspension followed by 5 years probation with conditions and \$10,000 fine.	Revocation and \$10,000 fine.	Same	Revocation.
(ddd) Being convicted of, or				

entering a plea of nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program. (Section 456.072(1)(ii), F.S.)				
First Offense	Misdemeanor – Reprimand, \$10,000 fine, suspension. Felony – Revocation.	Misdemeanor – \$10,000 fine, revocation. Felony – Revocation.	Revocation.	Revocation.
Second Offense	Misdemeanor or Felony – Revocation and \$10,000 fine.	Misdemeanor or Felony – Revocation and \$10,000 fine.	Same	Same
(eee) Failing to remit the sum owed to the state for any overpayment from the Medicaid program pursuant to a final order, judgement, or stipulation or settlement. (Section 456.072(1)(jj), F.S.)				
First Offense	\$1,000 fine, letter of concern.	\$10,000 fine suspension.	Reprimand and One (1) year Suspension.	Revocation or Denail of Application.
Second Offense	\$7,500 fine, reprimand.	\$10,000 fine, revocation.	Revocation.	Revocation.
(fff) Being terminated from the state Medicaid program pursuant to section 409.913, F.S., any other state Medicaid program, or the federal Medicare program, unless eligibility to participate in the program from which the practitioner was terminated has been restored. (Section 456.072(1)(kk), F.S.)				
First Offense	\$1,000 fine, letter of concern.	\$10,000 fine, suspension.	Reprimand and One (1) year Suspension.	Revocation or Denail of Application.
Second Offense	\$7,500 fine, reprimand.	\$10,000 fine, revocation.	Revocation.	Revocation.

(ggg) Being convicted of, or entering a plea of guilty or nolo contendere, to any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud. (Section 456.072(1)(ll), F.S.)				
First Offense	Misdemeanor – \$10,000 fine, reprimand. Felony – Revocation \$10,000 fine.	Misdemeanor – \$10,000 fine, suspension. Felony – Revocation \$10,000 fine.	Reprimand and One (1) year Suspension.	Revocation or Denial of Application.
Second Offense	Misdemeanor or Felony – \$10,000 fine, revocation.	Misdemeanor or Felony – \$10,000 fine, revocation.	Revocation	Revocation
(hhh) Failure to comply with the controlled substance prescribing requirements of section 456.44, F.S. (Section 456.072(1)(mm), F.S.)				
First Offense	Suspension of license for a period of six (6) months followed by a period of probation and an administrative fine in the amount of \$10,000.00.	Revocation and an administrative fine of \$10,000.00.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Suspension of license for a period of one (1) year followed by probation and an administrative fine in the amount of \$10,000.00.	Revocation and an administrative fine in the amount of \$10,000.00.	Six (6) month Suspension.	Revocation.
(iii) Providing false or deceptive expert witness testimony related to the practice of dentistry.				

(Section 466.028(1)(II), F.S.)				
First Offense	Reprimand and an administrative fine of \$5,000.00.	Revocation and an administrative fine of \$10,000.00.	Reprimand.	One (1) year Suspension or Denial of Application.
Second Offense	Revocation and an administrative fine of \$10,000.00.	Revocation and an administrative fine of \$10,000.00.	Six (6) month Suspension.	Revocation.
(jjj) Willfully failing to comply with section 627.64194 or 641.513, F.S., with such frequency as to indicate a general business practice. (Section 456.072(1)(oo), F.S.)			One (1) year Suspension.	Revocation.
First Offense	Reprimand and a \$5,000 fine.	Probation with conditions and \$7,500 fine.	Not Applicable to Telehealth Registrants.	
Second Offense	Reprimand; suspension for 6 months followed by Probation with Conditions; and \$8,000 fine.	\$10,000 Fine and revocation.	Not Applicable to Telehealth Registrants.	

(2) Based upon consideration of aggravating or mitigating factors, present in an individual case, except for explicit statutory maximum and minimum penalty requirements, the Board may deviate from the penalties recommended in subsection (1), above, and subsection (3), below. The Board shall consider as aggravating or mitigating factors the following:

- (a) The danger to the public;
- (b) The number of specific offenses, other than the offense for which the licensee is being punished;
- (c) Prior discipline that has been imposed on the licensee;
- (d) The length of time the licensee has practiced;
- (e) The actual damage, physical or otherwise, caused by the violation and the reversibility of the damage;
- (f) The deterrent effect of the penalty imposed;
- (g) The effect of the penalty upon the licensee;
- (h) Efforts by the licensee towards rehabilitation;
- (i) The actual knowledge of the licensee pertaining to the violation;
- (j) Attempts by the licensee to correct or stop the violation or refusal by the licensee to correct or stop the violation; and,
- (k) Any other relevant mitigating or aggravating factor under the circumstances.

(3) Penalties imposed by the Board pursuant to subsections (1) and (2), above, may be imposed in combination or individually, and are as follows:

(a) Issuance of a reprimand or letter of concern, which may be imposed in any disciplinary case, regardless of whether the penalty is referenced in any individual offense guideline;

(b) Imposition of an administrative fine not to exceed \$10,000.00 for each count or separate offense; for any violation found that is for fraud or making a false or fraudulent representation, the Board will impose a fine of \$10,000.00 per each count or offense, pursuant to section 456.072(2)(d), F.S. Unless stated otherwise in the disciplinary order, any imposed administrative fines are due within 90 days of the effective date of a final order imposing fines;

(c) Restriction of the authorized scope of practice or license. In taking disciplinary action against any person, whether or not the action also involves placing a licensee on probation, or imposing any penalty, the Board may impose restrictions on the practice or the license that include, but are not limited to the following:

1. Requiring remedial education as a requirement of continued practice,
2. Restricting the licensee from practicing in certain settings,
3. Restricting the licensee to work in only certain settings or under designated conditions,
4. Restricting the licensee from performing or providing designated clinical and administrative services,
5. Restricting the licensee from practicing a designated number of hours,
6. Any other restriction found to be necessary for the protection of the public health, safety, and welfare.

(d) Placement of the licensee on probation for a period of time and subject to such conditions as the Board may specify:

1. Probation Term. Unless otherwise specified above within each individual offense guideline, or unless a lesser period of time is stated in the order imposing probation, the period of probation will be for a period of five (5) years,

2. Probation Conditions. Probation conditions may include but not be limited to the following and may be imposed regardless of whether the term “conditions” is referenced in an individual offense guideline:

- a. Requiring the licensee to attend additional continuing education courses or remedial education,
- b. Requiring the licensee to pass an examination on the content and requirements of chapters 456 and 466, F.S., and division 64B5, F.A.C.,
- c. Requiring the licensee to work under the supervision of another licensee, including the submission of documents and reports from the supervisor and licensee,
- d. Tolling of the running of the probationary period when the licensee ceases to practice in Florida, or fails to maintain compliance with the probation requirements,
- e. Compliance with all terms of the order that imposes probation,
- f. Evaluation by an impaired practitioners network or program and entering or maintaining compliance with a recommended impaired practitioners program contract,
- g. Submitting to a continuing education audit for the next two consecutive biennial licensure renewal periods beginning with the date of the order imposing probation,
- h. Corrective action related to the violation, including but not limited to the repayment of any fees billed and collected from a patient or third party on behalf of the patient.
- i. The licensee is responsible for all costs associated with compliance with the terms of probation.

(e) Suspension of a license. Unless otherwise specified above within each individual offense guideline, or unless a lesser period of time is stated in the order imposing suspension, the period of suspension will be for a period of three years;

(f) Revocation of a license; which shall be permanent unless specified otherwise in the final order;

(g) Denial of an application for licensure, any violation of a provision of section 456.072(1) or 466.028(1), F.S., may be the basis for denial or issuance of licensure with restrictions or conditions; and,

(h) Costs. The licensee is responsible for payment of all costs of investigation and prosecution related to a disciplinary case. Additionally, all costs related to compliance with an order taking disciplinary action are the obligation of the licensee. Unless stated otherwise in the disciplinary order, any imposed costs are due within 90 days of the effective date of a final order imposing costs.

(4) The provisions of subsections (1) through (3), above, are not intended and shall not be construed to limit the ability of the Board to informally dispose of disciplinary actions by stipulation, agreed settlement or consent order pursuant to section 120.57(4), F.S.

(5) The provisions of subsections (1) through (4), above, are not intended and shall not be construed to limit the ability of the Board to pursue or recommend the Agency pursue collateral civil or criminal actions when appropriate.

*Rulemaking Authority 456.079(1) 456.47(7), FS. Law Implemented 456.072(2), 456.079(1), 456.47(4), 466.028 FS. History—New 12-31-86, Amended 2-21-88, 1-18-89, 12-24-91, Formerly 21G-13.005, 61F5-13.005, 59Q-13.005, Amended 4-2-02, 8-25-03, 2-27-06, 12-25-06, 6-11-07, 9-15-10, 12-2-10, 1-24-12, 4-25-17, 11-14-18.*

## CHAPTER 2019-137

### Committee Substitute for Committee Substitute for House Bill No. 23

An act relating to telehealth; creating s. 456.47, F.S.; defining terms; establishing standards of practice for telehealth providers; authorizing telehealth providers to use telehealth to perform patient evaluations; authorizing certain telehealth providers to use telehealth to prescribe certain controlled substances under specified circumstances; providing that a nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice is not deemed to be practicing medicine without a license; providing recordkeeping requirements for telehealth providers; providing registration requirements for out-of-state telehealth providers; requiring the Department of Health to publish certain information on its website; authorizing a board, or the department if there is no board, to take disciplinary action against a telehealth provider under certain circumstances; providing venue; providing exemptions from telehealth registration requirements; authorizing the applicable board, or the department if there is no board, to adopt rules; creating s. 627.42396, F.S.; providing requirements for a contract between a certain health insurer and a telehealth provider; amending s. 641.31, F.S.; providing requirements for a contract between a certain health maintenance organization and a telehealth provider; requiring the department to annually review the amount of certain collected fees and make a determination relating to the sufficiency of funding to implement specified telehealth provisions; upon making a certain determination, requiring the department to indicate insufficient funding and recommend fee adjustments in its annual legislative budget request; providing an appropriation; authorizing positions; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.47, Florida Statutes, is created to read:

456.47 Use of telehealth to provide services.—

(1) DEFINITIONS.—As used in this section, the term:

(a) “Telehealth” means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration. The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.

(b) “Telehealth provider” means any individual who provides health care and related services using telehealth and who is licensed or certified under s.

393.17; part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; who is licensed under a multi-state health care licensure compact of which Florida is a member state; or who is registered under and complies with subsection (4).

(2) PRACTICE STANDARDS.—

(a) A telehealth provider has the duty to practice in a manner consistent with his or her scope of practice and the prevailing professional standard of practice for a health care professional who provides in-person health care services to patients in this state.

(b) A telehealth provider may use telehealth to perform a patient evaluation. If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is not required to research a patient's medical history or conduct a physical examination of the patient before using telehealth to provide health care services to the patient.

(c) A telehealth provider may not use telehealth to prescribe a controlled substance unless the controlled substance is prescribed for the following:

1. The treatment of a psychiatric disorder;
2. Inpatient treatment at a hospital licensed under chapter 395;
3. The treatment of a patient receiving hospice services as defined in s. 400.601; or
4. The treatment of a resident of a nursing home facility as defined in s. 400.021.

(d) A telehealth provider and a patient may be in separate locations when telehealth is used to provide health care services to a patient.

(e) A nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice, as established by Florida law or rule, is not in violation of s. 458.327(1)(a) or s. 459.013(1)(a).

(3) RECORDS.—A telehealth provider shall document in the patient's medical record the health care services rendered using telehealth according to the same standard as used for in-person services. Medical records, including video, audio, electronic, or other records generated as a result of providing such services, are confidential pursuant to ss. 395.3025(4) and 456.057.

(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS.—

(a) A health care professional not licensed in this state may provide health care services to a patient located in this state using telehealth if the health care professional registers with the applicable board, or the department if there is no board, and provides health care services within the applicable scope of practice established by Florida law or rule.

(b) The board, or the department if there is no board, shall register a health care professional not licensed in this state as a telehealth provider if the health care professional:

1. Completes an application in the format prescribed by the department;
2. Is licensed with an active, unencumbered license that is issued by another state, the District of Columbia, or a possession or territory of the United States and that is substantially similar to a license issued to a Florida-licensed provider specified in paragraph (1)(b);
3. Has not been the subject of disciplinary action relating to his or her license during the 5-year period immediately prior to the submission of the application;
4. Designates a duly appointed registered agent for service of process in this state on a form prescribed by the department; and
5. Demonstrates to the board, or the department if there is no board, that he or she is in compliance with paragraph (e).

The department shall use the National Practitioner Data Bank to verify the information submitted under this paragraph, as applicable.

(c) The website of a telehealth provider registered under paragraph (b) must prominently display a hyperlink to the department's website containing information required under paragraph (h).

(d) A health care professional may not register under this subsection if his or her license to provide health care services is subject to a pending disciplinary investigation or action, or has been revoked in any state or jurisdiction. A health care professional registered under this subsection must notify the appropriate board, or the department if there is no board, of restrictions placed on his or her license to practice, or any disciplinary action taken or pending against him or her, in any state or jurisdiction. The notification must be provided within 5 business days after the restriction is placed or disciplinary action is initiated or taken.

(e) A provider registered under this subsection shall maintain professional liability coverage or financial responsibility, that includes coverage or financial responsibility for telehealth services provided to patients not located in the provider's home state, in an amount equal to or greater than the requirements for a licensed practitioner under s. 456.048, s. 458.320, or s. 459.0085, as applicable.

(f) A health care professional registered under this subsection may not open an office in this state and may not provide in-person health care services to patients located in this state.

(g) A pharmacist registered under this subsection may only use a pharmacy permitted under chapter 465, a nonresident pharmacy registered under s. 465.0156, or a nonresident pharmacy or outsourcing facility holding an active permit pursuant to s. 465.0158 to dispense medicinal drugs to patients located in this state.

(h) The department shall publish on its website a list of all registrants and include, to the extent applicable, each registrant's:

1. Name.
2. Health care occupation.
3. Completed health care training and education, including completion dates and any certificates or degrees obtained.
4. Out-of-state health care license with the license number.
5. Florida telehealth provider registration number.
6. Specialty.
7. Board certification.
8. Five-year disciplinary history, including sanctions and board actions.
9. Medical malpractice insurance provider and policy limits, including whether the policy covers claims that arise in this state.
10. The name and address of the registered agent designated for service of process in this state.

(i) The board, or the department if there is no board, may take disciplinary action against an out-of-state telehealth provider registered under this subsection if the registrant:

1. Fails to notify the applicable board, or the department if there is no board, of any adverse actions taken against his or her license as required under paragraph (d).
2. Has restrictions placed on or disciplinary action taken against his or her license in any state or jurisdiction.
3. Violates any of the requirements of this section.
4. Commits any act that constitutes grounds for disciplinary action under s. 456.072(1) or the applicable practice act for Florida-licensed providers.

Disciplinary action taken by a board, or the department if there is no board, under this paragraph may include suspension or revocation of the provider's registration or the issuance of a reprimand or letter of concern. A suspension may be accompanied by a corrective action plan as determined by the board, or the department if there is no board, the completion of which may lead to the suspended registration being reinstated according to rules adopted by the board, or the department if there is no board.

(5) VENUE.—For the purposes of this section, any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence. Venue for a civil or administrative action initiated by the department, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County.

(6) EXEMPTIONS.—A health care professional who is not licensed to provide health care services in this state but who holds an active license to provide health care services in another state or jurisdiction, and who provides health care services using telehealth to a patient located in this state, is not subject to the registration requirement under this section if the services are provided:

(a) In response to an emergency medical condition as defined in s. 395.002; or

(b) In consultation with a health care professional licensed in this state who has ultimate authority over the diagnosis and care of the patient.

(7) RULEMAKING.—The applicable board, or the department if there is no board, may adopt rules to administer this section.

Section 2. Effective January 1, 2020, section 627.42396, Florida Statutes, is created to read:

627.42396 Reimbursement for telehealth services.—A contract between a health insurer issuing major medical comprehensive coverage through an individual or group policy and a telehealth provider, as defined in s. 456.47, must be voluntary between the insurer and the provider and must establish mutually acceptable payment rates or payment methodologies for services provided through telehealth. Any contract provision that distinguishes between payment rates or payment methodologies for services provided through telehealth and the same services provided without the use of telehealth must be initialed by the telehealth provider.

Section 3. Effective January 1, 2020, subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(45) A contract between a health maintenance organization issuing major medical individual or group coverage and a telehealth provider, as defined in s. 456.47, must be voluntary between the health maintenance organization and the provider must establish mutually acceptable payment rates or payment methodologies for services provided through telehealth. Any contract provision that distinguishes between payment rates or payment methodologies for services provided through telehealth and the same services provided without the use of telehealth must be initialed by the telehealth provider.

Section 4. Effective July 1, 2020, the Department of Health shall annually review the amount of any fees collected under section 456.47, Florida Statutes, in the prior fiscal year and shall determine whether such fees are sufficient to enable the department and the boards, as defined in section 456.001, Florida Statutes, to fully implement section 456.47, Florida Statutes. If the department determines that the fees collected are insufficient, the department shall so indicate to the Legislature in its annual legislative budget request and shall recommend appropriate adjustments to the applicable fees.

Section 5. For fiscal year 2019-2020, the sums of \$261,389 in recurring funds and \$15,020 in nonrecurring funds from the Medical Quality Assurance Trust Fund are appropriated to the Department of Health, and four full-time equivalent positions with associated salary rate of 145,870 are authorized for the purpose of implementing s. 456.47, Florida Statutes, as created by this act.

Section 6. Except as otherwise provided, this act shall take effect July 1, 2019.

Approved by the Governor June 25, 2019.

Filed in Office Secretary of State June 25, 2019.



June 1, 2021

**J. Kendall Dillehay, DDS, MS**  
President



316.683.6518  
kdillehay@aaortho.org

**Norman Nagel, DDS, MS**  
President-Elect

805.581.2480  
nnagel@aaortho.org

**Myron D. Guymon, DDS, MS**  
Secretary-Treasurer



435.757.4542  
mguymon@aaortho.org

**Lynne Thomas Gordon, CAE**  
CEO

314.292.6512  
lthomasgordon@aaortho.org

Department of Health  
Florida Board of Dentistry  
Attention: Jessica Sapp  
4052 Bald Cypress Way  
Bin C-04  
Tallahassee, FL 32399-3258

Dear Members of the Florida Board of Dentistry:

I am writing to inform your dental board about recent changes to the American Association of Orthodontists' Clinical Practice Guidelines. Because dental boards have previously requested the AAO's Clinical Practice Guidelines for use as a reference regarding the standard of care for orthodontic treatment, the AAO wanted to assist you by providing the most up-to-date version of this document. **A copy of the revised AAO Clinical Practice Guidelines is enclosed with this letter.** The AAO invites and encourages you and your dental board to use the Guidelines as a resource for any matter in which you are required to consider the standard of care for orthodontic treatment (whether provided by an orthodontist, a general dentist or any other provider).

**The AAO has long been one of the foremost authorities on orthodontic practice.** As you may know, the AAO is the world's oldest and largest dental specialty organization, established in 1900. It represents more than 19,000 orthodontists throughout the United States, Canada, and abroad. The AAO is recognized, by both the American Dental Association and the National Commission on Recognition of Dental Specialties and Certifying Boards, as the sponsoring association for the national certifying board for orthodontists, the American Board of Orthodontics. The AAO's official journal, the *American Journal of Orthodontics and Dentofacial Orthopedics*, has been a leading peer-reviewed orthodontic resource since its establishment in 1915.

The AAO's Clinical Practice Guidelines, which represent the collective opinion of orthodontic experts regarding the best practices for the provision of safe and effective orthodontic treatment, are a trusted source for clinical insight and direction. Moreover, the Clinical Practice Guidelines are based upon peer-reviewed scientific literature and studies, as evidenced by the over 30 pages of citations attached to the Guidelines and upon which the Guidelines are based (*see* Guidelines, pp. 25-57).

**The revised Clinical Practice Guidelines now include recommendations specifically intended to protect patients receiving orthodontic treatment that includes a teledentistry component.**

The AAO understands that orthodontic treatment delivery systems are rapidly evolving, including many that incorporate some teledentistry or remote component. The AAO fully supports the incorporation of teledentistry into orthodontic treatment, **so long as the standards of care that best protect patient health and safety are not compromised.** For this reason, the revised Clinical Practice Guidelines make clear that **any** treatment model (including through use of teledentistry) should include certain elements to protect patient health and safety:

**Prior to the initiation of orthodontic or dentofacial orthopedic treatment, in order to enhance the health and safety of the patient, an in-person comprehensive dental and orofacial examination should occur by a state-licensed dentist. That dentist shall be currently practicing, and have a dental license in good standing, in the same state in which the comprehensive dental exam takes place. That dentist shall be searchable in the same state-run database and be able to be contacted by the patient.**

(Guidelines, p. 6, lines 36-41). The revisions to the AAO's Clinical Practice Guidelines reinforce the importance of protecting patients by specifying elements that should be included in any treatment, whether or not it includes the use of teledentistry.

**Also, the revisions to the Clinical Practice Guidelines clarify that they apply to anyone, not just orthodontists, providing orthodontic treatment, in order to best protect patient health and safety.**

Previously, the Clinical Practice Guidelines used a variety of words to refer to the individual responsible for elements of orthodontic treatment, including *practitioner*, *provider*, *clinician*, and *orthodontist*. The revised version replaces nearly all these references with the term *dentist* to underscore that **anyone** who provides orthodontic treatment should comply with these treatment guidelines. The Clinical Practice Guidelines now make clear that they **"encompass all licensed dental practitioners providing orthodontic care."** (Guidelines, p. 5).

Although the AAO believes any provider of orthodontic care should adhere to the best practices outlined in the Clinical Practice Guidelines, we firmly believe that orthodontic treatment is **best provided by an orthodontic specialist**. To that end, the Guidelines state: "The additional formal education of the orthodontist makes them the best qualified practitioner for management of orthodontic issues." (*Id.*).

I hope that this information will be helpful to you, your dental board, and board's staff in future matters. Please do not hesitate to contact me should you have any questions regarding the revisions to the AAO's Clinical Practice Guidelines, or in any instance where the AAO might be of assistance to you and your board.

Sincerely,



Trey Lawrence  
American Association of Orthodontists  
Vice President, General Counsel