American Association of Oral and Maxillofacial Surgeons
Oral and maxillofacial surgeons:
The experts in face, mouth and jaw surgery®

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Vanila Singh, MD
Chair, Pain Management Best Practices Inter-Agency Task Force
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
200 Independence Avenue SW
Room 736E
Washington, DC 20201

Dear Dr. Singh:

On behalf of the American Association of Oral and Maxillofacial Surgeons (AAOMS), the professional organization that represents 9,500 oral and maxillofacial surgeons (OMSs) in the United States, I would like to thank you for your leadership in seeking to address the nation's prescription drug abuse epidemic. The issue is a significant public health concern to our membership.

We applaud the effort members of the Pain Management Best Practices Inter-Agency Task Force will undertake over the next few months to identify, review and propose updates to gaps or inconsistencies between best practices for pain management, taking into consideration among other topics: existing pain management clinical practice and research; existing evidence-based guidelines; and state, local and medical professional organization's efforts. We are pleased to offer comments to the Task Force in response to your Federal Register notices on May 3, 2018 (83 FR 19565) and June 1, 2018 (83 FR 25469).

Oral and maxillofacial surgery is the surgical specialty of dentistry. As such, management of our patients' pain following invasive procedures is an important aspect of providing the best quality patient care. As lawful prescribers, we know, when used appropriately, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from surgical procedures. We also recognize, however, that pain medication prescribed following oral and maxillofacial surgery is frequently the first exposure many American adolescents have to opioids, and roughly 6.4 percent of all immediate-release opioid prescriptions in the United States are related to dental procedures.[1] Dentists, including OMSs, have a responsibility to ensure we do not exacerbate a growing public health risk while ensuring our patients receive the relief they need following complex dental procedures.

[1] Gupta N, Vujicic M, Blatz A. Opioid prescribing practices from 2010 through 2015 among dentists in the United States. JADA. 2018; 149(4): 237-245.

AAOMS is committed to educating our membership about the potential for opioid abuse. This is evidenced by the numerous resources and education, including continuing education courses presented through federal agencies, in which we have encouraged members to participate or we have offered. Specifically, AAOMS:

- Published **prescribing recommendations** for the management of acute and postoperative pain for the OMS patient that **urge non-narcotic pain management – rather than opioids – be utilized as a first-line therapy to manage a patient's acute and post-surgical pain.**
- Includes in nearly every AAOMS publication **information and resources for our membership about opioid abuse.**
- Partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA) to create the **free CE program, *Safe Opioid Prescribing for Acute Dental Pain*,** specifically for dentist prescribers. The online program launched in January 2016 and is available online to our members.
- Partnered with National Institute on Drug Abuse (NIDAMED) to **develop CE that teaches medical and dental prescribers how to talk to adolescents about substance abuse**. The CE program titled, "Research-Based Clinical Strategies to Prevent and Address Adolescent Substance Use and Prescription Medication Misuse – Being Part of the Solution," was released in June 2017.
- Makes **CE webinars available and hosts CE programs at AAOMS Annual Meetings** on opioid abuse that address pain management alternatives to opioids.
- Promotes the **Drug Enforcement Administration's National Prescription Drug Take Back Days** to our membership and encourages them to inform their patients.
- Developed educational materials for patients and caregivers, including an informational card on the **Safe Use and Disposal of Prescription Medications** that members can provide to their patients and communities.
- Participates in and promotes to our membership the **Partnership for Drug-Free Kids Medicine Abuse Project**.
- Partnered with Aetna to **study alternative post-operative pain management techniques** on their beneficiaries.

Our education efforts appear to be working. AAOMS conducted a survey of a random selection of OMSs in January 2017 and January 2018. The surveys showed a decline in the number of opioids being prescribed. For example, 79 percent of respondents in 2018 reported they reduced their opioid prescribing for third molar cases over the last two years. And 85 percent of respondents in 2018 reported prescribing less than a three-day supply of opioids following third molar surgery – an increase of 10 percentage points since last year.

Despite the positive changes in OMS prescribing trends, AAOMS recognizes a variety of factors contribute to the current opioid epidemic and more can be done to reduce opioid abuse and misuse.

As the Task Force deliberates on best practices for pain management, particularly as they relate to acute and post-surgical pain management, AAOMS submits for consideration our prescribing

recommendations for oral and maxillofacial surgeons. (The recommendations are attached). We further request the Task Force consider the possible need to establish a consistent definition of acute pain with review and input from stakeholders. At present, there does not appear to be a consistent definition of acute pain across federal agencies.

We also outline below the association's position on several other opioid-related topics if useful to the Task Force.

Federal Continuing Education
AAOMS supports CE on the topic of opioid abuse; however, AAOMS believes, to be most effective, CE should be managed at the state level because CE has traditionally been under the purview of the states. Additionally, CE should be appropriately proportionate to other CE requirements required to maintain state licensure and be customized so it is relevant to each type of prescribing situation. AAOMS further believes provider specialty organizations such as AAOMS should be included as accepted practitioner training organizations for CE requirements.

Prescription Drug Monitoring Programs
AAOMS supports properly funded prescription drug monitoring programs (PDMPs) that are updated in real time by dispensers and interoperative between states. Furthermore, approved auxiliary personnel should be authorized to access the system on the prescriber's behalf so doctors have adequate time to provide quality patient care. Finally, it should not be mandatory for prescribers to check a PDMP for acute pain patients who receive an opioid prescription of less than seven days following an invasive surgical procedure, as the risk of abuse and diversion is low in these instances.

Prescribing Initiatives
AAOMS appreciates the development of prescribing guidelines and, as noted, the association recently developed prescribing recommendations that urge non-narcotic pain management be utilized as a first-line therapy to manage an OMS patient's acute and post-surgical pain. AAOMS believes any effort by government entities to develop prescribing guidelines should recognize the unique care provided by OMSs by both involving them in the development process and avoiding a one-size-fits-all approach as pain management needs vary from patient to patient. Furthermore, AAOMS supports efforts by appropriate agencies to secure approval of innovative solutions for alternative pain management options, which would reduce the need for opioids. This would include pharmaceuticals that extend the length of surgical site anesthesia, such as bupivacaine HCI.

If the federal government considers imposing a national dosage limitation restriction, AAOMS encourages any such restrictions to allow provider discretion because the management of pain severity varies by procedure and patient. Finally, AAOMS advocated in support of a provision in the Comprehensive Addiction and Recovery Act (P.L. 114-198) that would clarify federal law to allow pharmacies to partially fill a Schedule II drug, when allowed by state law. Federal efforts to encourage states to allow patients to obtain part of their prescription with the option to acquire the remaining amount only when necessary would lessen the risk of diversion of unused medications.

Safe Disposal of Opioids

Finally, it is imperative that patients have the ability to easily and safely discard unused medication from their medicine cabinets to minimize the risk of misuse and diversion. While many community-based prescription take-back programs exist, manufacturers can play a role in expanding these programs. Therefore, AAOMS supports efforts that would require the FDA to work with manufacturers to establish programs for the efficient return or destruction of unused prescription drugs.

AAOMS commends the task force and its volunteers on providing guidance to curb the misuse of prescription drugs. We welcome an opportunity to discuss these issues in greater detail and work with you to explore other possible solutions. Please contact Jeanne Tuerk, manager of the AAOMS Department of Governmental Affairs, at 800-822-6637 or jtuerk@aaoms.org for additional information.

Sincerely,

Brett L. Ferguson, DDS, FACS
AAOMS President

Attachment

White Paper

American Association of Oral and Maxillofacial Surgeons

Opioid Prescribing: Acute and Postoperative Pain Management

Oral and maxillofacial surgeons must demonstrate safe and competent opioid prescribing for acute and postoperative pain in their patients. Responsible prescribing of opioids must be a priority, including accessing the state's prescription-drug monitoring program as well as educating the patient and family about potential risks – and the safe use, storage and disposal – of opioid analgesics. Because prescribing protocols evolve over time, practitioners also should stay informed of the latest public health trends, including possible alternatives to opioid pain treatment.

It is the position of AAOMS that the practitioner-patient relationship must be upheld, allowing for practitioner judgment in the management of a patient's pain – including drug types, dosages and treatment durations. Pain management decisions should be individualized and only determined after a careful assessment of the level of risk to – and condition of – the patient. While oral and maxillofacial surgeons should ultimately make all final prescribing decisions, the recommendations in this AAOMS White Paper are intended to provide direction and serve as a supportive resource.

Considerations and recommendations for the management of acute and postoperative pain include the following:

- A nonsteroidal anti-inflammatory drug administered pre-emptively may decrease the severity of postoperative pain.
- A perioperative corticosteroid (dexamethasone) may limit swelling and decrease postoperative discomfort after third-molar extractions.
- A long-acting local anesthetic (e.g., bupivacaine, etidocaine, liposomal bupivacaine) may delay onset and severity of postoperative pain.
- The oral and maxillofacial surgeon should avoid starting treatment with long-acting or extended-release opioid analgesics.
- Providers should prescribe non-steroidal anti-inflammatory drugs (NSAIDs) as first-line analgesic therapy, unless contraindicated. If NSAIDs are contraindicated, providers should prescribe acetaminophen (N-acetyl-p-aminophenol [APAP]) as first-line analgesic therapy.
- NSAIDs and APAP, taken simultaneously, work synergistically to rival opioids in their analgesic effect, but dosage levels and times of administration should be carefully documented to prevent overdosage.
- When indicated for acute breakthrough pain, consider short-acting opioid analgesics. If opioid analgesics are considered, start with the lowest possible effective dose and the shortest duration possible.
- When prescribing opioids, state law may require prescribers to access the state prescription drug-monitoring program (PDMP). If there is any suspicion of patient drug misuse, abuse and/or addiction, the OMS should access the PDMP. To assess for opioid misuse or addiction, use targeted history or validated screening tools.
- All instructions for patient analgesia and analgesic prescriptions should be carefully documented.
- When deviating from these prescribing recommendations – or those required by state laws or institutions – the oral and maxillofacial surgeon should document the justification for doing so.

Oral and maxillofacial surgeons also should:

- Address exacerbations of chronic or recurrent pain conditions with non-opioid analgesics, non-pharmacological therapies and/or referral to specialists for follow-up, as clinically appropriate.
- Limit the prescriptions of opioid analgesics to patients currently taking benzodiazepines and/or other opioids because of the risk factors for respiratory depression.

- Inform patients that the recommended maximum daily dose of acetaminophen should not exceed 3,000 mg. To avoid potential APAP toxicity, an oral and maxillofacial surgeon choosing to prescribe an opioid should consider one that is ibuprofen-based.
- Counsel patients that the recommended maximum daily dose of ibuprofen is 3,200 mg. Note: Higher maximal daily doses have been reported for osteoarthritis while under the direction of a physician.
- Educate patients on the expectations of postoperative pain management and the anticipated levels of relief.
- Not prescribe acetaminophen with codeine to treat pain in children younger than 12. For more information, visit the FDA Drug Safety site.

For management of chronic pain, refer to the Centers for Disease Control's Guideline for Prescribing Opioids for Chronic Pain.