



Pharmacologic and PPE shortages

As the surgical branch of dentistry – and the bridge to medical colleagues – oral and maxillofacial surgeons (OMSs) provide vital services that are urgent, emergent and outpatient in nature. OMS offices function as small, independent operatories with OMSs who diagnose and treat conditions related to the maxillofacial complex. They provide office-based sedation and anesthesia on a daily basis to patients who would otherwise not tolerate treatment outside a hospital operating room. In addition, OMSs are vital to the management of dental-related emergencies that, if left untreated, can quickly become life-threatening. Such outpatient treatment provides a significant cost savings to the patient and lessens both the patient load on hospital emergency rooms and the financial burden on the health system at large – all of which were especially important in the wake of the COVID-19 pandemic.

Their unique skillset and largely independent status make OMSs prone to shortages of pharmaceuticals and supplies, including personal protective equipment (PPE). These shortages are further exacerbated by the fact that the independent nature of OMS practices limits buying power afforded to hospitals and large group practices, further restricting access to necessary supplies and increasing susceptibility to price gouging due to relatively small purchase power.

Pharmacologics

Over the past two decades, 3,260 drugs have been reported in shortage with an average of 142 new drugs reported in shortage each year.¹ These shortages are due to many factors, including regulation issues with the FDA, manufacturing delays and production quality concerns, shipping issues (both domestic and international), company mergers and lack of profitability to produce. Reduced access to these vital pharmaceuticals has a significant impact on patient care, as alternative drugs may be more expensive or produce other untoward side effects.

In order to provide invaluable outpatient services, OMSs need access to pharmacologics – including anesthetics, analgesics, antibiotics, antiemetics,

emergency medications (e.g., epinephrine, ephedrine, glycopyrrolate, atropine, adenosine) and saline, just to name a few. When such medications are unavailable – or at significantly elevated prices, as is typical during shortage periods – OMSs cannot offer the same high level of care to patients, significantly impacting the healthcare system.

The solution to pharmaceutical shortages is complex and requires a multifaceted approach. Many drugs in shortages have small margins of profit for the manufacturers but are, nonetheless, essential for healthcare. It is important to incentivize manufacturers to produce these critical drugs as well as invest in quality management to ensure their extensive and consistent availability. The Food and Drug Administration Safety and Innovation Act, the first comprehensive federal legislation to address drug shortages signed into law in 2012, required enhanced reporting by drug manufacturers when they anticipated a manufacturing interruption and discontinuance.² Congress took additional steps in 2022 to address ongoing shortages by including several provisions in the Consolidated Appropriations Act of 2023. Most notably, the law requires a study on providing incentives to encourage domestic production for certain generic medicines and requires the FDA to issue guidance for manufacturers on extending drug expiration dates.³

The American Association of Oral and Maxillofacial Surgeons (AAOMS) urges additional coordination between the Department of Health and Human Services (HHS) and Department of Justice (DOJ) to address controlled substances in short supply, including increasing production quotas and removing some regulations to allow manufacturers to adapt to market shifts. The Association further recommends Congress investigate the development of a nonprofit, similar to programs currently serving several hospital systems, to assist office-based professionals in securing pharmacologics.

PPE

The U.S. healthcare system was paralyzed by medical supply shortages at the height of the COVID-19 pandemic. Many providers outside the large hospital systems found

it difficult, if not impossible, to obtain proper PPE and, where available, prices were exorbitant. When OMSs are unable to provide PPE for their staff and themselves, it is not possible to continue caring for these patients.

During the beginning of the COVID-19 pandemic, many officials discriminated against OMSs due to their dental training and failed to recognize the important role the profession plays in the healthcare system. AAOMS has urged all levels of government to recognize OMSs as essential frontline providers and allocate fair distributions of PPE during national shortage periods so emergent cases may continue to receive treatment outside hospital emergency rooms. AAOMS also has encouraged national efforts to secure the supply chain by incentivizing domestic manufacturing and developing an early notification system, similar to the FDA pharmaceutical program, for supply shortages. Congress included in the Consolidated Appropriations Act of 2023 several provisions to help mitigate supply shortages such as requiring ongoing reviews of the Strategic National Stockpile (SNS) to confirm its contents are sufficient and ready for deployment, ensuring domestic manufacturing capabilities can be rapidly produced and stored, helping states shore up their respective stockpiles and providing a transparent process for how the federal government will distribute materials from the SNS to states and other eligible entities.³ AAOMS further encourages Congress and state legislatures to empower Attorneys General and their relevant agencies to go after unscrupulous vendors who price gouge during critical events, such as national pandemics.

White Paper



References:

- 1 *American Society of Health-System Pharmacists. [ASHP.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics?loginreturnUrl=SSOCheckOnly](https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics?loginreturnUrl=SSOCheckOnly). Accessed December 2023.*
- 2 *Food and Drug Administration Safety and Innovation Act (P.L. 112-144). [Govinfo.gov/content/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf](https://www.govinfo.gov/content/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf).*
- 3 *Consolidated Appropriations Act of 2023 (P.L. 117-328). [Congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf](https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf).*

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